



Kansas Department of Health and Environment  
Bureau of Child Care and Health Facilities  
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## **Annual Risk Management Report for 2008**

“Life Happens!”

Life is full of accomplishments, plateaus, and challenges. Sometimes things happen so rapidly that we do well just to “hang on” and keeping up with the changes is never ending. Life happens!

As challenges mount, ability to provide services meeting standards of practice (or at all), let alone exceeding standards to reach facility goals, may seem impossible. Staff, on all levels, may become frustrated as they find themselves unable to keep up with perceived or mandated job responsibilities.

Administration, including those involved directly in risk management, has both a responsibility and an opportunity to set the tone for the facility. Will it be nurturing or punitive?

In a nurturing setting, consequences are given fairly and justly (“just” culture) when behavior does not meet standards of practice and/or facility standards. Nurturing is defined as to “nourish,” “educate,” and “train.”

Unfortunately, many individuals were raised and/or live in a punitive environment. Punitive is defined as inflicting or aiming at punishment. Punish means “hurt.” Consequences given in a punitive setting would be imposed as a penalty. This penalty –actual or fear of - would be perceived as the driving factor to maintain order versus the opportunity to improve found in a nurturing “just” culture setting.

The ancient proverb “For Want of a Nail” is still relevant today. This proverb describes a small undesirable situation (need for nail) that mushrooms:

- 1) Failure to replace the nail leads to the loss of a horse shoe.
- 2) The lost horse shoe leads to the death of the horse.
- 3) The death of the horse leads to the death of the rider.
- 4) The loss of the rider leads to a lost battle.
- 5) The lost battle leads to a lost kingdom. Just because of a missing horseshoe nail.

Does your facility have any small problems that, left uncorrected, may become expensive and possibly deadly? In 1986, the space shuttle Challenger exploded 73 seconds after blast off and killed all seven aboard. The cause: a faulty O-ring valued at less than a dollar! The investigation identified that NASA (National Aeronautics and Space Administration) managers had been aware of the potentially catastrophic flaw in the O-rings since 1977, but failed to take appropriate action. This failure cost the lives of seven people, impacted innumerable others, and shut the space program down for 32 months. All because, the managers disregarded the engineers' warnings.

Benjamin Franklin said, "An ounce of prevention is worth a pound of cure." This quote applies to risk management. Properly applied, risk management will be more proactive (prevention) than reactive (damage control/corrective action striving for a cure).

On 7/11/08, Joe Tye, America's Values Coach, wrote in his article, "Never Fear Trying, Never Quit Caring," excerpts from his book, Never Fear, Never Quit. Mr Tye quoted Confucius as saying that "to see what is right and not to do it is cowardice." Also the reverse is true. To do what you know is right, even when it is difficult or unpopular, is courage. Caring is the root of courage and gives a person the courage "to never fear trying," and do what is right. To complete the risk management process effectively, takes caring and courage.

Coretta Scott King said, "It doesn't matter how strong your opinions are. If you don't use your power for positive change, you are, indeed, part of the problem." Mark Twain stated, "The secret of getting ahead is getting started. The secret of getting started is breaking your complex overwhelming tasks into small manageable tasks, and then starting on the first one. " Both quotations carry a lot of wisdom for managing risk. No one wants to have a "Challenger disaster" at their facility.

Based on many factors, CMS (Centers for Medicare and Medicaid Services) determined that ASCs (Ambulatory Surgery Centers) required expansion of regulatory oversight. These factors included:

- 1) More than 38 percent increase in number of ASCs during the period of 2002 – 2007
- 2) Fifteen percent of ASCs surveyed in FY (Fiscal Year) 2008 had serious (condition-level) deficient practices
- 3) Hepatitis C outbreak in Nevada during CY (Calendar Year) 2008 traced to poor infection control practices in two ASCs. More than 50,000 former patients were notified of potential exposure and reportedly more than 100 people developed Hepatitis C as a result of their exposure in the ASCs
- 4) Subsequent surveys of Nevada ASCs found 64 percent had serious problems, primarily in infection control

These findings lead to development and pilot testing in 2008 (by three states - Maryland, Oklahoma, and North Carolina) of a new infection control survey instrument and use of tracer methodology (following at least one patient through the entire course of their ASC experience). Of the 68 ASCs surveyed during the pilot testing, approximately 19 percent had condition-level deficiencies and 85 percent had standard-level deficiencies, primarily in the area of infection control. Common deficient practice included use of single-dose medication vials for multiple patients, improper sterilization practices, general disinfection, sanitation, and failure to have a system for reporting notifiable disease to their respective State health agency.

Findings did not go unheeded. Actions were taken by the Federal government that would become effective in 2009. Kansas would become one of the first states to apply the new protocols.

In September 2008 at a CMS sponsored Midwest Consortium meeting *Leading the Path to Collaboration: Pressure Ulcer Prevention and Care*, an identified goal was the establishment of a committee of stakeholders to promote collaborative efforts to reduce the prevalence of pressure sores. On 11/3/08, the Pressure Ulcer Collaboration was established in Kansas. Representatives from the full spectrum of pressure ulcer care and prevention were invited to join the Collaborative. These included consumers, providers of all types, affiliated associations, and regulatory agencies. Many of those invited are now participating in the Collaboration. The Collaboration, as a whole, meets every other month - beginning with the 11/3/08 initial meeting, and sub-committees meets monthly. The Collaboration's goal is to develop and promote tools and resources that will improve communication and facilitate pressure ulcer prevention and treatment at all levels of care. The Risk Management Specialist participates in this Collaboration and is also a member of the Care Transition Team sub-committee.

While Kansas is ahead of many states because our risk management program has been in place for more than 20 years, there is always room for improvement. The current risk management regulations are under review by KDHE (Kansas Department of Health and Environment) and provider affiliated agencies, organizations and associations, for possible revision. Many aspects of patient safety and "just culture" are being considered for inclusion. Everyone wants to live in a safe environment and be treated justly.

Members from KARQM (Kansas Association of Quality and Risk Managers) and KHA (Kansas Hospital Association) continue to meet with KDHE in order to improve communication between these entities in regard to the risk management process. Our goal is to continue an open dialogue so we may learn from each other and improve the quality of care in Kansas medical care facilities.

KDHE publishes an annual report with aggregate data collected from the risk management quarterly reports, but these results cannot establish a system to enhance quality improvement. The quarterly report form includes a section for medical care facilities to document systematic changes they have implemented to improve patient care and minimize the occurrences of medical errors. Approximately 20 % of the facilities completed this part of the quarterly report during 2008.

The book To Err is Human, written by the Institute of Medicine in 1999, emphasized that the medical field will never be able to completely stop medical errors, as the staff that order, prepare and administer the care are human and humans do make mistakes. But it is very clear that **if** we improve the processes of ordering, preparing and administering care, these improvements will assist us "humans" from making some of these errors. Should there ever be a wrong site surgery? No, not if the process is in place that would prevent anyone from operating on the wrong limb or the wrong eye. Pre-operative surgical site designation and "time out" has become the standard. Yet in Kansas, we continue to have wrong site surgeries reported.

It has been 20 years since this book was published, but the book continues to a quoted resource. Improvements have been made, but we are not there yet. We must find a better way to communicate potential problem areas and encourage medical care facilities to implement safer practices – "an ounce of prevention." Staff, patients and families must be empowered. Patient safety must be put first above egos and personal agendas. Many facilities are striving for excellence. The Just Culture and Patient Safety First protocols continue to be steps in the right direction.

Because the definition for an adverse event is not universal it is impossible to compare data from state to state. The definition for adverse or a sentinel event from the Joint Commission on Accreditation of Healthcare Organization is “an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function.” Colorado’s definition is “All deaths arising from unexplained causes or under suspicious circumstances. Brain and spinal cord injuries. Life-threatening complications of anesthesia. Life-threatening transfusion errors or reactions. Burns; missing persons; physical, sexual, and verbal abuse; neglect; misappropriation of property; diverted drugs; malfunction or misuse of equipment.” New York’s definition is “An unintended adverse and undesirable development in an individual patient’s condition occurring in a hospital.” A list of 36 occurrences (reduced from 47) that must be reported follows the definition.

In Kansas, a reportable adverse event includes all occurrences when the standard of care was not met and injury occurred or was probable. Kansas’s adverse events also include incidents that were possible grounds for disciplinary action by the appropriate licensing agency of the involved individual, such as, unprofessional conduct. Many of the adverse events reported in Kansas, would not be reported to these other entities.

Even with the best of the best, things do not always go as planned and hoped. Life happens! Under risk management, providers are given an opportunity to candidly evaluate the event and make corrective action as warranted.

### *Brief History of Kansas Risk Management*

This report represents the twentieth in a series written by KDHE staff. The report outlines the issues, problems, findings, and significant changes which have occurred in the implementation of the Kansas Risk Management law (KSA 65-4921 et. Seq.). In 1987, House Bill 2661 passed requiring every medical care facility in Kansas to establish an internal risk management program. On September 1, 1987, Bill Rein was named as the Director of Quality Assurance and Risk Management to provide oversight for the new legislative mandate. In 1988, risk management surveys began with annual surveys of 160 facilities by two Risk Management Specialists.

In 1996 following passage of House Bill 2867, combination licensure and risk management surveys for all non-accredited hospitals and ASCs (Ambulatory Surgical Centers) were initiated to assure compliance. Two Risk Management Specialists surveyed the 187 facilities at least every three years. In late 2008, KDHE completed some Risk Management surveys at a later date than the routine survey of the facility. This action reduced the ability to review areas of concern identified in the routine survey during the risk management survey, per the KDHE protocol for a combination survey. However, benefits have greatly outweighed any disadvantages. Primary benefits for a risk management focused survey were the potential for a more accurate evaluation of a facility’s risk management program and a much greater opportunity for the provision of risk management education, when indicated.

The 1997 article, entitled “The Kansas Risk Management Program: What Has Changed and What Remains the Same,” explored the changes and early implementation efforts brought on by passage of House Bill 2867. That article explained the conceptual process of incorporating risk management laws and statutes with existing state licensure regulations into a revised “standards review” which had not been conducted in a number of years. A limitation on similar Medicare surveys was a result of revised federal funding priorities. The article presented the philosophy and

development of a new survey instrument, a summary of the types and frequency of deficiencies cited during the initial reviews, as well as statistics historically gathered on risk management reporting to licensing agencies.

New risk management statutes were passed in 1997 that included peer review and designated reports, records, and proceedings as confidential and privileged. On February 27, 1998, new risk management regulations became effective to enforce the new statutes. The January 1999 article, entitled "Two Years of Experience and Lessons Learned" reviewed the new regulations. The regulations were designed to reflect what had become recognized as the basic standards for risk management programs across the state.

"Striving for a Better Tomorrow," submitted in 2000, reviewed the survey process for 1998 and 1999. The role of the medical facility surveyor continued to be primarily that of a regulator but also increased as an educator to hospitals and ambulatory surgical centers concerning the protection of risk management information, the need of the risk managers to become more proactive with observation and record review to ascertain possible risk management problems, and for risk managers to become more involved with minimizing patient adverse events.

"To Error is Human, BUT can be Deadly" (submitted in 2001) reviewed the risk management program for calendar year 2000. There was an increase in the government and the public's awareness of medical errors with a demand that something must be done to protect patients from medical errors. The emphasis is placed on improving processes in order to minimize occurrences.

"Creating a Safer Health Environment," (submitted in 2002) outlined the categories that states are using to develop risk management programs. The categories were established as criteria to be included in the development of the state programs.

While Kansas has accomplished most of these steps, the last step – enhancing/sustaining quality improvement - continues to be one that is most difficult to accomplish. One of the recommendations for completing this step is that states establish a coalition for the prevention of medical errors. The coalition would determine approaches for alerting and informing facilities about the risk of errors and develop practices for addressing identified problems. The states that have established this coalition have done so with members from all licensing agencies involved with the prevention of medical errors. Members from KARQM and KHA meet with KDHE in order to improve communication between these organizations/agencies in regard to the risk management process.

"Reduction of Preventable Errors – A Mandate, Not an Option" (submitted for 2003) stressed the high toll from hospital errors. On July 28, 2004, the National Academy for State Health Policy released a bulletin entitled, "Higher toll cited from hospital errors," by Scott Allen, Globe Staff. The article identified medical mistakes as the third-leading cause of death in the United States, behind heart disease and cancer. The article quoted Dr Samantha Collier, vice president of medical affairs at HealthGrades, which publishes rankings of hospitals and doctors. According to Dr Collier, "There is little evidence that patient safety has improved in the last five years." "The equivalent of 390 jumbo jets full of people are dying each year due to likely preventable, in-hospital medical errors, making this one of the leading killers in the US." The analysis used a broad definition of medical error. The definition changed to include cases in which hospital staff failed to respond quickly to signs of infection or other dangerous problems accounted for almost the entire

increase in the number of deaths. The group noted that the increase in deaths came almost entirely from adding “failure to rescue” the patient as a medical error.

HealthGrades identified 195,000 deaths annually from 2000 - 2002 and estimated that Americans paid an extra \$19 billion in medical costs for the victims of these mistakes. Studies repeatedly showed that medical errors were widespread and harmed up to one in every 25 patients admitted to the hospital.

Many hospitals now have “rescue” teams that are activated whenever a patient’s status changes or fails to improve. These teams are empowered to “take charge” of the patient’s care, if indicated.

“Effective Risk Management” (submitted for 2004) emphasized the importance of a proactive risk management program. According to an April 2005 AARP (American Association of Retired Persons) bulletin, only 10% of the 84% of physicians who observed co-workers taking shortcuts, that could be dangerous to patients, reported what they saw. Additionally, infection control continued to be an on-going challenge. A March 2005 RN magazine article, “VAP Prevention, the latest guidelines,” stressed the risk to patient on mechanical ventilation and reported that one-third of the patients who develop VAP die. This article emphasized that the key to prevention is prevention of cross contamination, by appropriate gloving and gowning and washing hands with soap and water or alcohol-based antiseptic hand rub before and after contact.

“Putting the Patient’s Safety First” (submitted for 2005) focused on the benefits and obstacles of implementing Just Culture and Patient Safety First protocols. Many facilities have mission statements including the provision of ultimate care to all patients. These statements often come with many unwritten “ifs” – if staff has time, if it doesn’t cost too much, if it won’t upset the surgeon, if ... If your care is impacted by unwritten “ifs,” the facility should evaluate priorities and give patient care and patient safety it’s rightful place.

“The Triumphs and Challenges of Emergency Medicine” (submitted for 2006) spot lighted emergency medicine’s progress and shortcomings. On 6/13/07 an Associated Press release entitled “Woman dies in ER lobby as 911 refuses to help” stunned all who heard or read the release. The common questions were “What went wrong?” and “How could this happen?” We still don’t have all the answers, but many hospitals have taken corrective action, as a result of this death.

“Managing Medical Technology and Other Risk Management Challenges” (submitted for 2007) addressed the rapid development of medical technology and the challenges related to these changes. Staff are responsible for not only the patient, but also the equipment. Patients occasionally report that the only time staff touched them or spoke to them was purely in the course of performing a task. No matter how sophisticated technology has become, it has not be able to replicate the human touch. Technology coupled with human expertise are a winning combination benefiting both recipients and healthcare providers.

### *Ambulatory Surgical Centers*

KDHE implemented a revised certification, licensure and risk management survey process for ASCs in the spring of 2001 using the revised state regulations approved in April 2001. In FY 2008, CMS mandated that the states:

- 1) complete ASC surveys for 10% of the state's non-accredited ASCs each year for compliance with federal regulations,
- 2) complete additional surveys to insure that no more than seven years elapses between surveys of any one ASC provider, and
- 3) ensure that all ASC providers are surveyed at least every six years, on average.

As medical care changes and the need to stay overnight after surgery becomes less prevalent, the number of ASCs continues to grow. In 1987, there were eight ASCs licensed in the state of Kansas. As of December 31, 2008, there were sixty-seven ASCs.

### *Acute Care and Critical Access Hospitals*

Implementation of the new combined licensure/survey process for medical care facilities began on December 1, 1996. The goal was to survey each hospital at least every two and a half to three years. In 2000, federal certification requirements for resurveys in non-accredited hospitals were increased from 5% to 33% each year. In 2006, federal certification frequency requirements were lengthened to a resurvey every six years. Since many of the regulations are similar, the federal certification resurvey and licensure/risk management processes were combined to meet the increased workload. In FY 2008, CMS mandates that the states:

- 1) complete targeted surveys each year for compliance with federal regulations and ensure that no more than five years elapses between surveys for any one particular non-accredited hospital or non-accredited critical access hospital for not less than 5% of each of the two types of hospitals;
- 2) complete additional surveys to insure that no more than 4.5 years elapses between surveys of any one particular non-accredited hospital or non-accredited critical access hospital, and
- 3) ensure that all non-accredited hospital or non-accredited critical access hospital are surveyed at least every three years, on average.

Kansas continues to lead the states in the number of CAHs. As of December 31, 2008, there were 83 Critical Access Hospitals in Kansas. Converting to a CAH has not demonstrated any changes in the risk management outcomes. Hopefully, the supporting hospitals will assist the CAHs in developing proactive and effective risk management and quality improvement programs. The goal is for these developments to lead to an overall improvement in patient safety and quality of care.

### *Risk Management Issues*

Confidentiality of Risk Management information continues to be at the forefront of discussions between risk managers and associated organizations. Confidentiality concerns are associated with the Adams vs. St. Francis Regional Medical Center's decision of releasing the relevant facts and the Unzueta vs. Schalansky decision when the plaintiff's attorney was given access to all of the risk management investigational interviews of witnesses, both staff and patients. Although the mental impressions, decision-making processes, and conclusions of hospital personnel involved in the risk management or peer review processes continue to be protected, there is concern from risk managers that this may change in the future.

The Director of Medical Facilities and the Risk Management Specialist met with members of members of KARQM and KHA in 2001 to discuss risk management concerns. This group, along with the State Survey Manager, continues to meet on an ongoing basis to work on developing meaningful interpretations of these definitions. The goals of the meetings are to ensure a more

universal reporting system for Kansas and to improve communication between associations and organizations that play a part in the risk management process.

Surveyors answer risk management questions during the risk management survey process. On an on-going basis, the Risk Management Specialist is available to provide education and answer questions for the medical care facilities. Many Kansas facilities had a changeover of risk managers during the interim between surveys. Per survey findings and as reported by risk management staff, some new and experienced risk managers fail to protect the reporter's name, to assure that risk management information is secured at all times, and/or to take immediate action when an error occurs. These risk managers do not investigate "near misses" and/or identifying root causes to pinpoint effective interventions, including improved processes, to further minimize occurrences. The risk management surveyors evaluate the facilities for compliance with the Kansas Risk Management statutes and regulations and with implementation of an effective risk management program.

Risk management regulation KAR 28-52-4 mandates that facilities assign a separate standard of care for each involved provider, and each issue. Finding the individual providers involved with the incident and determining a standard of care for those providers has been the focus of risk management for many years. Beginning in 2000, we saw a trend by facilities to place an emphasis on looking at the process of care not just the individuals involved. This does not mean that the risk management committees can discontinue reviewing individuals involved in the adverse event and assigning the individuals a standard of care. The trend of looking at the process as well as the individual is encouraged by KDHE. Frequently, the root cause is a process problem that precipitated staff's substandard performance. Assessing the process and making improvements on those processes demonstrates a proactive approach to minimizing future occurrences. As the Institute of Medicine Committee on Quality of Health Care in America reports in the book To Err is Human: Building a Safer Health System (1999), people in all lines of work make errors. Errors **can be prevented** by designing systems that make it harder for people to do the wrong thing and easier for people to do the right thing. This is also stressed in all "Patient Safety First" applications. We need to build safer systems by designing processes of care that will ensure that patients are safe from accidental injury.

### *The Risk Management Specialist*

The KDHE's Risk Management Specialist is involved in many risk management activities. Those activities included, but were not limited to:

- 1) Review and approval of new and amended risk management plans;
- 2) Response to inquiries about state and federal regulations and the risk management process;
- 3) Review of adverse events and their corrective action as reported by facilities;
- 4) Review of facilities' quarterly reports;
- 5) Education of new facility applicants of risk management requirements;
- 6) Provision of consultation and presentation of workshops and training to risk managers and hospital personnel throughout the state;
- 7) Provision of consultation and training to KDHE surveyors;
- 8) On-site surveys; and
- 9) Creation of the annual risk management report.



The turnover of risk managers throughout the state continues and many are placed in their positions without training or orientation. In 2008, the Risk Management Specialist provided educational programs for medical care facilities throughout the state, both in a group setting and on an individual basis.

### *Medical Facility Survey Process*

Each hospital should anticipate that the survey process takes approximately one week to complete. An ASC survey, depending on size, will take approximately one to three days. When deficiencies are cited, the facility may receive a revisit within six months. A survey revisit is usually accomplished in four to eight hours. The new ASC protocols, effective in 2009, will increase ASC survey hours. This will usually be accomplished by increasing the number of surveyors on the team, not the actual number of survey days.

### *Citing a Deficiency*

During the survey process, surveyors observe care provided to patients, review medical records for appropriate documentation, review facility policies for the required elements, conduct patient, family and/or staff interviews, and observe the physical environment of the facility. During the survey if the surveyor identifies that the facility's practice is not consistent with the regulatory requirement, a deficiency is written at the appropriate regulatory code/tag.

In order to assure that facilities are not cited twice for the same deficiency, surveyors will cite only the federal regulation if the deficient practice violates both state and federal requirements. There are no regulations for risk management in the federal regulations. Due to confidentiality, all risk management deficiencies are cited on a separate state deficiency statement.

### *Risk Management Goals for 2009*

The Bureau of Health Facilities Risk Management continuous goals are to:

- Assist facilities in improving the risk management process through educational programs and consultation;
- Share information accumulated from literature, the direct involvement with other states and the direct involvement with federal coalitions/organizations;
- Monitor facility risk management programs through the survey process;
- Improve communication between state licensing agencies concerning specific cases.

KDHE believes that it is important to maintain and improve communication between licensing agencies, medical care facilities, and professional organizations in order to reach these goals. Questions related to the medical care facilities' licensure and/or risk management may be directed to:

Lynn Searles RN, Risk Management Specialist or  
Charles Moore, Director of Medical Facilities and Survey Support  
Bureau of Child Care and Health Facilities  
Kansas Department of Health and Environment  
1000 SW Jackson, Suite 200  
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Statistical Information

for

Risk Management/Licensure and Certification

Survey Process

# ***Glossary of Terms***

## ***Tables***

## ***Appendices***

## ***Frequently Cited Tags***

## ***Glossary of Terms***

<b>AHRQ</b>	Agency for Healthcare Research and Quality
<b>ASC</b>	Ambulatory Surgical Center
<b>BCCHF</b>	Bureau of Child Care and Health Facilities
<b>CAH</b>	Critical Access Hospital
<b>CDC</b>	Centers for Disease Control
<b>CFR</b>	Code of Federal Regulations
<b>CMS</b>	Centers for Medicare and Medicaid Services
<b>CY</b>	Calendar Year
<b>FY</b>	Fiscal Year
<b>KAR</b>	Kansas Administrative Regulations
<b>KARQM</b>	Kansas Association of Quality and Risk Managers
<b>KDHE</b>	Kansas Department of Health and Environment
<b>KHA</b>	Kansas Hospital Association
<b>KSA</b>	Kansas Statutes Annotated
<b>KSBHA</b>	Kansas State Board of Healing Arts
<b>KSBN</b>	Kansas State Board of Nursing
<b>KSPB</b>	Kansas State Pharmacy Board
<b>MDS</b>	Minimum Data Set
<b>NASA</b>	National Aeronautics and Space Administration
<b>NASHP</b>	National Academy for State Health Policy
<b>NCPS</b>	National Center for Patient Safety
<b>SB MDS</b>	Swing Bed Minimum Data Set
<b>SOC</b>	Standard of Care
<b>TAGS</b>	(Survey Reference)

## **Tables Introduction**

Historically data has been presented to medical care facilities related to the number of incidents confirmed to meet standard of care determination levels 3 or 4, the agency to which the incident was reported, and the number of reports generated by facility size. These figures are updated through the end of 2008 and are presented in the following tables.

**Table 1\***  
Comparison of Reportable Incidents By Year and By Licensing Agency 2001 – 2008

Year	Total # of Reportable SOCs	SOC III	SOC IV	KSBHA	KSBN	KDHE	KSBP	Other
2001	436	320	116	48 (11%)	208(48%)	149(34%)	14(3%)	17 (4%)
2002	501*	395	106	57 (12%)	222 (47%)	149 (34%)	14 (3%)	16 (3%)
2003	572***	447	126	22(16.1%)	43 (31.4%)	62(45.3%)	8(5.8%)	2 (1.4%)
2004	519****	388	131	61(11.3%)	233(43%)	219(40.4%)	10(1.8%)	19(3.5%)
2005	640****	371	269	44(6.9%)	339(53%)	219(34.2%)	22(3.4%)	16(2.5%)
2006	531*****	427	104	68(12.8%)	243(45.8%)	166(31.3%)	32(6%)	22(4.1%)
2007	548*****	412	136	71(13%)	249(45.4%)	196(35.8%)	18(3.3%)	14(2.5%)
2008	703*****	532	171	59(8.4%)	401(57%)	214(30.5%)	14(2%)	15(2.1%)

\***Table 1** above depicts the number of incidents reported to licensing agencies for the years 2001-2008. .

\*\*The 2002 total number of SOCs by all providers was 93,627 with 501 SOC IIIs and SOC IVs or .535%.

\*\*\*The 2003 total number of SOCs by all providers was 87,359 with 572 SOC IIIs and SOC IVs or .655%, an increase.

\*\*\*\*The 2004 total number of SOCs by all providers was 89,306 with 519 SOC IIIs and SOC IVs or .581%, a decline.

\*\*\*\*The 2005 total number of SOCs by all providers was 96,726 with 640 SOC IIIs and SOC IVs or .66%, an increase.

\*\*\*\*\*The 2006 total number of SOCs by all providers was 107,293 with 631 SOC IIIs and SOC IVs or .485%, a decline.

\*\*\*\*\*The 2007 total number of SOCs by all providers was 101,447 with 548 SOC IIIs and SOC IVs or .54%, an increase.

\*\*\*\*\*The 2008 total number of SOCs by all providers was 109,072 with 703 SOC IIIs and SOC IVs or .645%, an increase.

**Table 2**

Comparison of Total Number of **Reportable Incidents** Generated By Facility Size and Licensing Agency  
2001-2008

Facility Size	Year	KSBHA	KSBN	KDHE	Pharmacy	Other
1-25 beds	2008	25(17%)	84(57.2%)	31(21.1%)	3(2%)	4(2.7%)
	2007	16(10.5%)	79(51.9%)	48(31.6%)	5(3.3%)	4(2.7%)
	2006	21 or 12.1%	61 or 35.3%	55 or 31.8%	15 or 8.7%	21 or 12.1%
	2005	16 or 9.5%	59 or 34.9%	89 or 52.4%	2 or 1.2%	3 or 1.8%
	2004	18 or 14%	40 or 31%	59 or 46%	1 or 1%	10 or 8 %
	2003	19 (13.6%)	79 (56.5 %)	32 (22.8%)	8 (5.7 %)	1 (1.4%)
	2002	6 or 7%	29 or 32%	53 or 38%	1 of 1%	3 or 3 %
	2001	4 or 5%	36 or 45%	34 or 42%	1 or 1%	6 or 7%
26-50 beds	2008	2(3%)	40(60.7%)	22(33.3%)	0	2(3%)
	2007	15(38.5%)	15(38.5%)	9(2.23%)	0	0
	2006	2 or 6.5%	16 or 51.6%	1 or 3.2 %	3 or 9.7%	9 or 29%
	2005	1 or 3.3%	20 or 66.7%	8 or 26.7%	0	1 or 3.3%
	2004	4 or 6%	29 or 40%	39 or 54%	0	0
	2003	23 or 23.9%	35 or 38%	28 or 34.4%	5 or 5.4%	1 or 1%
	2002	9 or 13%	38 or 53%	22 or 31%	3 or 4%	0
	2001	17 or 24%	36 or 50%	20 or 28%	3 or 4%	3 or 4%
51-100 beds	2008	3(2.2%)	110(82.1%)	18(13.4%)	2(1.5%)	1(.8%)
	2007	5(10.2%)	23(51%)	12(24.5%)	1(2%)	5(10.2%)
	2006	15 or 22.4%	44 or 65.7%	0	1 or 1.5%	7 or 10.4%
	2005	3 or 3.9%	41 or 53.2%	13 or 16.9%	16 or 20.8%	4 or 5.2%
	2004	5 or 12%	24 or 56%	7 or 16%	2 or 5%	5 or 12%
	2003	4 or 11%	17 or 41.5%	15 or 36.6%	0	2 or 4.9%
	2002	6 or 9%	25 or 36%	34 or 49%	2 or 3%	2 or 3%
	2001	4 or 11%	21 or 54%	9 or 24%	0	4 or 11%
101-200 beds	2008	4(26.7%)	5(33.3%)	4(26.7%)	0	1(13.3%)
	2007	15(25.9%)	29(50%)	4(6/9%)	9(15.5%)	1(1.7%)
	2006	13 or 36.1%	18 or 50%	1 or 2.8%	0	4 or 11.1%
	2005	4 or 9.3%	35 or 81.4%	2 or 4.6 %	0	2 or 4.6%
	2004	18 or 17%	65 or 65%	21 or 19%	3 or 3%	1 or 1%

Facility Size	Year	KSBHA	KSBN	KDHE	Pharmacy	Other
	2003	0	10 or 52.6%	9 or 47.4%	0	0
	2002	9 or 17%	36 or 67%	8 or 15%	1 or 2%	0
	2001	6 or 11%	38 or 69%	10 or 18%	0	1 or 2%
201+ beds	2008	21(6.3%)	160(47.9%)	139(41.6%)	8(2.4%)	6(1.8%)
	2007	16(7%)	101(41%)	122(50%)	3(1%)	3(1%)
	2006	13 or 6.5%	96 or 47.8%	5 or 2.5%	6 or 3%	81 or 40.3%
	2005	18 or 5.3%	181 or 57.8%	104 or 33.2%	4 or 1.3%	6 or 1.9%
	2004	14 or 10%	2 or 19%	91 or 65%	4 or 3%	3 or 2%
	2003	19 or 48.7%	1 or 2.5 %	17 or 41.5%	1 or 2.6%	1 or 2.6%
	2002	13 or 8%	87 or 50%	59 or 34%	8 or 5%	6 or 3 %
	2001	17 or 9%	85 or 45%	76 or 40%	10 or 5%	3 or 1%
	ASCs	2008	4(57.1%)	2(28.6%)	0	1(14.3%)
2007		3(43%)	0	3(43%)	0	1(14%)
2006		4 or 20%	8 or 40%	0	1 or 5%	7 or 35%
2005		2 or 25%	3 or 37.5%	3 or 37.5%	0	0
2004		2 or 29%	3 or 43%	2 or 28%	0	0
2003		0	0	0	0	0
2002		1 or 8%	0	3 or 23%	0	9 or 69%
2001		0	0	0	0	0

**\*Table 2.** compares the total number of incidents reported by facility size and licensing agency, including percentages of reports to agencies by facility size and year.



**Table 3**

Comparison of Average Number of Incidents Reviewed and Total Number of Reportable Incidents Filed By Facility Size 2005 – 2008

Facilities by Bed Size/ Category	Number of Facilities in Size Category 2008	Avg # of SOC's/ Total # of Reportable SOC's 2005	Avg # of SOC's/ Total # of Reportable SOC's 2006	Avg # of SOC's/ Total # of Reportable SOC's 2007	Avg # of SOC's/ Avg # of Reportable SOC's /Avg # of Incidents 2008
1 - 25	93	296.9/169	351/176	408.4/152	380.4/1.6/250.8
26 - 50	13	492.8/30	501.8/31	544.2/39	1329.4/5.1/942.8
51 - 100	25	555.8/77	596.8/67	524.9/49	615.3/5.7/586.3
101 - 200	13	703.4/43	1049/36	1221.5/58	517.2/1.2/447.1
200 +	13	2873/313	3044/201	2701/243	4661.3/25.7/3955.6
ASCs	65	39.6/8	37/20	34.8/7	35.6/10.8/24.7
Totals	222	469.5/640	506.1/531	501.9/548	620.2/3.2/481.3

\***Table 3** above compares the average number of SOC determinations reviewed and the total number of SOC determinations reported, by facility size. The average number would equate to item number 4 on the Kansas Department of Health and Environment Confidential Quarterly Report form, while the total figure would represent item number 4 (c) and 4 (d) on the same form. The bed size is based on the acute bed count as determined by a facility's license. For example, a facility licensed for 20 acute beds and 60 long-term care beds would be included in the 1-25 bed grouping. Mental health, mental retardation, and psychiatric hospitals are listed by total bed count.

## KDHE RISK MANAGEMENT ARTICLES

1. **"Risk Management Defined"** discusses the history of risk management enabling legislation (House Bill 2661). This article attempts to explain the purposes for requiring risk management programs, the elements necessary to meet statutory requirements, and plans for KDHE's first survey cycle. The article was written in 1988.
2. **"Health Care Risk Management in Kansas: 1990 Issues"** attempts to answer the eight most frequently asked questions about risk management laws during KDHE's first survey cycle. Those questions include: What is the essence of the risk management law? Why are hospital committees required to determine standards of care in individual cases? What is necessary to assure that standards of care are met? How must an investigation be accomplished to meet the requirements of state risk management laws? The article was written in 1989.
3. **"The Failures of Risk Management"** addresses the early problems faced by risk management programs. Those problems included administrative turnover, failure to document provider- and issue-specific standard of care determinations, lack of incident reporting logs sufficient to assure that each case received a standard of care determination, and lack of executive committee oversight. The article also discusses KDHE objectives for its third risk management survey cycle. This article was written in 1990.
4. **"A Statutory Approach to Hospital Risk Management: Five Years in Kansas"** reviews the history of risk management programs from 1987 to 1991. In addition, the article discusses the results of over 200 interviews with direct care staff concerning risk management program in 64 facilities. This article was written in 1991.
5. **"Five Years of Risk Management in Kansas: An Overview"** was published in The Kansas Nurse and provides an overview of the risk management program from a nursing perspective. The article was written in 1992.
6. **"Kansas Risk Management Laws: Report and Observations on the First Three Survey Cycles"** describes the survey cycles implemented by KDHE. Comparisons of incident reporting activities by aggregate facility size to types of licensing agencies are made. The article was written in 1993.
7. **"Resident Abuse, Neglect, and Exploitation and the Kansas Risk Management Law"** describes the role of the risk management law in relation to other federal and state statutes related to allegation of resident abuse in facilities. The article was written in 1994.
8. **"Compliance of Facilities with Kansas Risk Management Surveys: An Update"** provides statistics related to risk management activities from 1988 through 1993. The article was written in 1994.
9. **"Rationale: The Basis for Standard of Care Decisions"** explores the importance of developing clear and reasonable documentation in risk management investigations. The article was written in 1995.
10. **"The Kansas Risk Management Law: Does it need to be Redesigned for the Future?"** discusses the history of risk management in Kansas and its relationship to other quality assurance and quality improvement efforts. The article was written in 1995.
11. **"Final Risk Management Site Review Statistics through Survey Year VI"** provides an overview of compliance history and incident reporting during six risk management survey cycles. The article was written in 1996.

12. **“The Kansas Risk Management Program: What Has Changed and What Remains the Same”** describes the changes occurring in medical care facility licensure laws following passage of 1996 House Bill 2867. The implementation of a state licensure/risk management survey process is discussed and statistics from early surveys are presented. The article was written in 1997.
13. **“Two Years of Experience and Lessons Learned”** describes the experience of combining the licensure/risk management survey. Provides information on the Adams vs. St Francis court case, which opened up some of the facts of risk management. Introduced the new regulations, which were intended to provide further guidance to medical care facilities in implementing the provisions of KSA 65-4922. This article was written in 1999.
14. **“Striving for a Better Tomorrow”** describes the new role of the Risk Management Specialist, adding an educational component, the start of a new quarterly report, which would give corrective action for trending issues as well as the individual. This article was written 2001.
15. **“On-site Licensure/Risk Management Surveys: “To Error is Human” - BUT Can Be Deadly”** describes the change of focus from looking at only individuals involved with incidents to an emphasis of looking at the process of care. This does not mean that the risk management committees can discontinue reviewing the individuals involved in the adverse event, but the facility should also review the process involved. Errors can be prevented by designing systems that make it hard for people to do the wrong thing and easy for people to do the right thing. We need to build safer systems by designing processes of care to ensure that patients are safe from accidental injury. Patients need assurance that the process of care will proceed correctly and safely so they have the best chance possible of achieving desired outcomes. Written 2001.
16. **“Dirty Bed,”** by Michael J Berens for The Chicago Tribune, reported that dirty hospitals kill 75,000 patients a year, unnecessarily. The article noted 50% of the doctors and nurses in hospitals do not clean their hands between patients. The article was written in 2003.
17. **“Higher toll cited from hospital errors”** by Scott Allen, Globe staff. The article identified medical mistakes as the third-leading cause of death in the United States, behind heart disease and cancer. The article quoted Dr Samantha Collier, vice president of medical affairs at HealthGrades, which publishes rankings of hospitals and doctors. This article was written in 2004.
18. **“VAP Prevention, the latest guidelines,”** describes this type of pneumonia as a frequent complication of patients on ventilators for 48 hours or more. Up to one third of the patients developing VAP die. Prevention of cross contamination is paramount to preventing VAP. The article was written in 2005.
19. **“Errors Associated with Medications Removed from Automated Dispensing Machines Using Override Function,”** Hospital Pharmacy, reports on the problems and solutions related to staff overrides of these machines. The article was written in 2006.
20. **“Plague of Errors,”** by John Buntin, focuses on the cause and effect of rising hospital rates. With infection rates escalated by 36 % since 1975, approximately 5 % of hospital patients contract a nosocomial infection, each year that results in 90,000 deaths. The article was written in 2005.
21. **“Stamping out surgical site infections,”** RN Magazine, stress the impact of 500,000 surgical site infections annually in the US. Possible causes include failure to adhere to CDC guidelines for pre-operative antimicrobials with a reported 25 – 50 % misuse. The article was written in 2006.
22. **“Patients Have Better Outcomes in Most Wired Hospitals,”** by Debra Wood RN, NurseZone.com. Patients have better outcomes in “wired hospitals as hospitals turn to technology to assist with care. The article appeared in July 2007.

23. **“Parkland ER launches self-service check in,”** news release at Parkland Hospital website describes the innovative approach to improve management of emergency department patients. The article was released 6/20/07.
24. **“One-third of ED communications are interruptions, contributing to medical errors,”** by Brixey and colleges, in the *International Journal of Medical Informatics*, reported on a case study conducted in a Level One Trauma Center at a teaching hospital. The article appeared in June 2007.
25. **“Woman dies in ER lobby as 911 refuses to help”** was released by the Associated Press and related the events leading to the death of a 43 year-old woman in a hospital waiting area. The article was released on 6/13/07.
26. **“Technology: Friend or For?”** by David Harrington, PHD, discussed examples of what happens when entities embrace or fail to embrace cost cutting technology. Article released in December 2006.
27. **“Electronic Health Records: Useful Tools or High-Tech Headache?”** by Roxanne Nelson, BSN, RN, in the *American Journal of Nursing*, candidly spoke to the pros and cons of the electronic health record. Article appeared in March 2007.
28. **“Electronic Medical Records: Friend or Foe?”** by Patrick Romero. reported on President Bush’s 2014 goal for Electronic Medical Record usage and progress toward that goal. The article was released on 5/14/08.
29. **“Slim, Flexible Stents Approved to Treat Heart Disease,”** by Adam Voiland, describes the new generation of drug-coated stents. The article was released on 7/8/08.
30. **“Part 2: Bar-Coding & Implanting Humans Is Here,”** by Brenda Miller, in the *Edge*, reported on implantation uniquely identified GPS (Global Positioning System) devices in humans. The article appeared in September 2005.
31. **“RFID vs Medical Devices; Friend or Foe,”** by Dr Hazem El-Orady, spoke to the Dutch study published in the 6/25/08 Journal of American Medical Association. The article was released in The Medical Informatics Portal on 7/15/08.
32. **“Wireless Technology Friend or Foe?”** an undated brochure by the US Department of Homeland Security, educates the public on “rogue” wireless access and countermeasures.
33. **“When It’s Surgery, Don’t Get It Wrong,”** by Tracy Grant, in the Washington Post, relates a near miss experience and related research. The article appeared on 7/22/08.
34. **“Heparin Errors Continue Despite Prior, High-Profile, Fatal Events,”** in the *Institute for Safe Medication Practices*, reports on continuing problems in this area, including multiple errors in July 2008 in a Texas hospital. The article appeared on 7/17/08.
35. **“Never Fear Trying, Never Quit Caring,”** by Joe Tye, in *Spark Plug’s Weekend Spark*, encourages individuals to be courageous and do the right thing. The article appeared on 7/11/08.
36. **“For Want of A Nail Rhyme,”** Famous quotes UK and Rhymes.org.uk
37. **“Space Shuttle Challenger disaster,”** Wikipedia
38. **“American Recovery and Reinvestment Act of 2009 (Recovery Act) Ambulatory Surgical Center Healthcare-Associated Infection (ASC-HAI) Prevention Initiative,”** CMS S&C-09-43, 6/12/09



## APPENDIX B

Total of Survey Codes Cited During 53 Critical Access Hospital Licensure and Certification Surveys 2008

SURVEY CODES	# of CITES	SURVEY CODES	# of CITES	SURVEY CODES	# of CITES	SURVEY CODES	# of CITES
H0007	1	C0226	1	C0301	1	C0372	2
H0010	2	C0229	6	C0302	4	C0373	2
H0011	1	C0230	1	C0304	3	C0374	1
H0035	1	C0240	2	C0305	1	C0379	1
H0038	1	C0241	5	C0306	1	C0381	1
H0042	1	C0244	1	C0307	37	C0385	8
H0043	1	C0250	1	C0308	6	C0386	3
H0044	2	C0252	1	C0309	1	C0395	3
H0059	1	C0258	1	C0320	2	C0396	4
H0062	1	C0259	1	C0322	2	C0399	1
H0063	3	C0260	3	C0323	1	C0404	2
H0114	1	C0263	1	C0330	3	C2400	1
H0115	1	C0264	1	C0331	5	C2402	1
H0117	1	C0270	2	C0332	2	C2405	1
H0119	1	C0271	2	C0333	6	C2407	1
H0123	1	C0272	8	C0334	5	C2409	1
H0125	1	C0273	1	C0335	3		
H0138	2	C0274	1	C0336	2		
		C0275	1	C0337	1		
C0195	1	C0276	13	C0338	3		
C0201	1	C0278	5	C0339	3		
C0202	1	C0279	1	C0340	1		
C0203	1	C0280	6	C0345	1		
C0205	2	C0281	2	C0360	1		
C0207	4	C0282	2	C0364	1		
C0211	1	C0283	2	C0366	1		
C0222	5	C0291	1	C0368	1		
C0223	3	C0292	1	C0369	1		
C0224	1	C0294	4	C0370	1		
C0225	15	C0298	7	C0371	1		

## APPENDIX C

Total of Survey Codes Cited During 16 **Ambulatory Surgical Center** Licensure and Certification Surveys  
2008

SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED
S0500	1	S0740	1	Q0034	1
S0530	1	S0800	1		
S0535	1				
S0575	2	Q0002	1		
S0615	1	Q0003	1		
S0620	1	Q0006	2		
S0640	1	Q0009	1		
S0720	1	Q0011	1		

## APPENDIX D

Total of Survey Codes cited During 67 Hospital, CAH and ASC **Risk Management** Surveys 2008

SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED	SURVEY CODES	NUMBER OF FACILITIES CITED
R0800	1	R0809	3	R0829	1
R0801	4	R0811	1	R0830	1
R0802	8	R0813	4	R0831	1
R0803	1	R0819	3	R0832	7
R0805	1	R0820	1	R0833	14
R0807	1	R0826	1	R0835	1
R0808	2	R0828	1	R0836	1

## APPENDIX E

Most Frequently Cited Survey Codes and Percentage of Facilities Cited During 41 **Hospital** Certification & Licensure 2008

Survey Code	Number of Times Survey Code Cited	Percentage of Facilities Cited
A0396 – Nursing Care Plan	9	22%
A0450 – Medical Record Services	8	19.5%
A0701 – Maintenance of Physical Plant	7	18.7%
A0749 – Infection Control Officer Responsibilities	7	18.7%
A0395 – RN Supervision of Nursing Care	6	14.6%
A0392 – Staffing and Delivery of Care	5	12.2%

## APPENDIX F

Most Frequently Cited Survey Codes and Percentage of Facilities Cited During 53 **CAH Hospital** Certification Surveys 2008

Survey Code	Number of Times Survey Code Cited	Percentage of Facilities Cited
C0307 - Record System	37	69.8%
C0225 – Maintenance	15	20.3%
C0276 - Policies – Drug Management	8	15.1%
C0385 - Patient Activities - 483.15(f)	8	15.1%
C0272 - Policies – Developed with Advice of Group of Professional Personnel	7	13.2%



## APPENDIX G

Most Frequently Cited Survey Codes and Percentage of Facilities Cited During 58 **Hospital & CAH** Risk Management Surveys 2008

Survey Code	Number of Times Survey Code Cited	Percentage of Facilities Cited
R0833 – Separate SOC per provider and clinical issue	14	24.1%
R0802 – Risk Management activities documented and reported	7	12%
R0832 – Appropriate SOC determination	7	12%

## APPENDIX H

Most Frequently Cited Survey Codes and Percentage of Facilities Cited During **ASC** Surveys – 16 Certification & Licensure and 9 Risk Management Surveys 2008

Survey Code	Number of Times Survey Code Cited	Percentage of Facilities Cited
Q0006 – Anesthetic Risk and Evaluation	2	12.5%
S0575 – Infection Control	2	12.5%

# APPENDIX I

## *2008 Cited Survey Codes*

### **State Licensure and Federal Certification Acute Care Hospital:**

H0007        **KAR 28-34-3a(g)** The external disaster plan shall be rehearsed at least twice a year, preferably as part of a coordinated drill in which other community emergency service agencies participate. The drills shall involve professional, administrative, nursing and other hospital personnel.

H0010        **KAR 28-34-3b(a)(10)** Each patient is informed of the facility's policies regarding patient rights during the admission process.

H0035        **KAR 28-34-7(i)** Minutes shall be kept of nursing staff meetings.

H0037        **KAR 28-34-8a(b)** The chief executive officer. The governing body shall appoint a chief executive officer. The qualifications, responsibilities, duties and authority of the chief executive officer shall be described in a written statement adopted by the governing body. The chief executive officer implement policies established by the governing body for the operation of the hospital and shall act as a liaison between the governing body, medical staff and the departments of the hospital.

H0042        **KAR 28-34-8a(d)(3)** Personnel records. Accurate and complete personnel records shall be maintained for each employee. Personnel records shall contain at least the following information for each employee's records of the initial health examination and subsequent health services and periodic health evaluations.

H0043        **KAR 28-34-8a(e)** Education programs. Orientation and in-service training programs shall be provided to allow personnel to improve and maintain skills and to learn of new health care developments.

H0044        **KAR 28-34-8a(f)** Personnel health requirements. Upon employment, all hospital personnel shall have a medical examination which shall consist of examinations appropriate to the duties of the employee, including a chest X-ray or tuberculin skin test. Subsequent medical examinations or health assessments shall be given periodically in accordance with hospital policies. Each hospital shall develop policies and procedures for control of communicable disease, including maintenance of immunization histories and the provision of educational materials for patient care staff.

H0059        **KAR 28-34-9a(f)** Each entry in each record shall be dated and authenticated by the person making the entry. Verbal orders shall include the date and signature of the person recording them. The prescribing practitioner shall authenticate the order within 24 hours. Records of patients discharged shall be completed within 30 days following discharge.

H0063        **KAR 28-34-1a(d)** Pharmacy and therapeutics committee. Each hospital shall establish a pharmacy and therapeutics committee or its equivalent. The committee shall consist of at least physicians, nurses and pharmacists. This committee shall assist in the formulation of broad professional policies regarding evaluation, appraisal, selection, procurement, storage, distribution and use of drugs and safety procedures and all other matters relating to drugs in the hospital. This committee shall meet at least quarterly, record its proceedings and report to the medical staff.

H0113        **KAR 28-34-18a(c)(2)** Each delivery room shall have access to the following:  
(A) Equipment appropriate for maternal and newborn resuscitation, including suction, airways, endotracheal tubes, and ambu bags;  
(B) Equipment for administration of inhalation and regional anesthetics;

- (C) A functioning source of emergency electrical power;
- (D) An emergency call or intercommunication system;
- (E) Oxygen and suction equipment which can be accurately regulated;
- (F) A fetal monitor;
- (G) Supplies and instruments for emergency Cesarean section;
- (H) A scrub sink with foot, knee, or elbow control;
- (I) Prophylactic solution approved by the licensing agency for instillation into eyes of newborn pursuant to K.S.A. 64-153 and K.A.R. 28-4-73 and any amendments thereto;
- (J) A method for identification of the newborn and mother;
- (K) A movable, heated bassinet, a bassinet with a radian warmer, or a transport isolette for the newborn while in the delivery room and during transport from the delivery room; and
- (L) A sink with foot, knee, or elbow control.

H0114           **KAR 28-34-18a(c)(3)** Each normal or neonatal intensive care nursery shall have access to the following:

- (A) A bassinet or isolette for the exclusive use of each infant and for storage or individualized equipment and supplies;
- (B) Oxygen, oxygen analyzer, and suction equipment which can be accurately regulated;
- (C) Phototherapy light
- (D) Intravenous infusion solutions and equipment. A pump shall also be available;
- (E) ; Sink with foot, knee, or elbow control; and
- (F) Newborn resuscitation equipment.

H0115           **KAR 28-34-18a(d)(1)** Each entry in each record shall be dated and authenticated by the person making the entry. Verbal orders shall include the date and signature of the person recording them. The prescribing practitioner shall authenticate the order within 24 hours. Records of patients discharged shall be completed within 30 days following discharge.

H0117           **KAR 28-34-18a(d)(3)** Newborn services shall provide for newborn recovery, observation, and isolation, and for high-risk infants, access to care in a neonatal intensive care nursery either at the hospital of birth or by transfer to a hospital with a neonatal intensive care unit.

H0119           **KAR 28-34-18a(e)** Policies and procedures. The directors of the obstetrical and newborn services, in cooperation with nursing service, shall develop procedures and policies which shall be available to the medical and nursing staff. Minimal procedures shall include the following:

H0123           **KAR 28-34-18a(e)(4)** Each newborn shall be transported to the mother's room or other units outside the nursery in an individual basis.

H0125           **KAR 28-34-18a(e)(6)(A)** Additional policies shall be adopted concerning, at minimum, the following: (A) The use of oxytocic drugs and the administration of anesthetics, sedatives, analgesics, and other drugs;

H0138           **KAR 28-34-18a(f)** Perinatal committee. The hospital shall establish an obstetrical and newborn services committee to monitor, evaluate, and recommend the provision of patient services. The committee membership shall include appropriate medical and nursing staff personnel.

***(Multiple versions of "A" tags in effect)***

A0023           **CFR 482.11(c)** The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.

A0050 **CFR 482. 12(a)(7)** [The governing body must] ensure that criteria for selection are individual character, competence, training, experience, and judgment.

A0083 **CFR 482. 12(e)** The governing body must be responsible for services furnished in the hospital whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services.

A0084 **CFR 482. 12(e)(1)** The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.

A0115 **CFR 482.13** A hospital must protect and promote each patient's rights.

A0117 **CFR 482.13(a)(1)** A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

A0118 **CFR 482. 13(a)(2)** The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.

A0119 **CFR 482.13(a)(2)** The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.] The hospital's governing body must approve and be responsible for the effective operation of the grievance process, and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee.

A0120 **CFR 482.13(a)(2)** The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization. At a minimum:

A0121 **CFR 482.13(a)(2)(i)** The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.

A0122 **CFR 482.13(a)(2)(ii)** At a minimum:  
The grievance process must specify time frames for review of the grievance and the provision of a response.

A0123 **CFR 482.13(a)(2)(iii)** At a minimum:  
In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

A0130 **CFR 482.13(b)(1)** The patient has the right to participate in the development and implementation of his or her plan of care.

A0131 **CFR 482.13(b)(2)** The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care.

The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

- A0133 **CFR 482.13(b)(4)** The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.
- A0143 **CFR 482.13(c)(1)** The patient has the right to personal privacy.
- A0144 **CFR 482.13(c)(2)** The patient has the right to receive care in a safe setting.
- A0145 **CFR 482.13(c)(3)** The patient has the right to be free from all forms of abuse or harassment.
- A0147 **CFR 482.13(d)(1)** The patient has the right to the confidentiality of his or her clinical records.
- A0156 **CFR 482.21(c)(2)** Performance improvement activities must implement preventive actions and mechanisms that include feedback and learning throughout the hospital.
- A0158 **CFR 482.13(e)** [Restraint or seclusion] must be discontinued at the earliest possible time.
- A0162 **CFR 482.13(e)(1)(ii)** Seclusion is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving.
- A0164 **CFR 482.13(e)(2)** Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient or others from harm.
- A0166 **CFR 482.13(e)(4)(i)** The use of restraint or seclusion must be in accordance with a written modification to the patient's plan of care.
- A0168 **CFR 482.13(e)(5)** The use of restraint or seclusion must be in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with State law.
- A0169 **CFR 482.13(e)(6)** Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN).
- A0170 **CFR 482.13(e)(7)** The attending physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion.
- A0171 **CFR 482.13(e)(8)** [Unless superseded by State law that is more restrictive,] after 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c) of this part and authorized to order restraint or seclusion by hospital policy in accordance with State law must see and assess the patient.
- A0172 **CFR 482.13(e)(8)** [Unless superseded by State law that is more restrictive,] after 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c) of this part and authorized to order restraint or seclusion by hospital policy in accordance with State law must see and assess the patient.
- A0174 **CFR 482.13(e)(10)** The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff that have completed the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy.

- A0175 **CFR 482.13(e)(10)** The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff that have completed the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy.
- A0176 **CFR 482.13(e)(11)** Physician and other licensed independent practitioner training requirements must be specified in hospital policy.
- A0178 **CFR 482.13(e)(12)** When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1-hour after the initiation of the intervention by a physician or other licensed independent practitioner; or registered nurse or physician assistant who has been trained in accordance with the requirements specified in paragraph (f) of this section.
- A0179 **CFR 482.13(e)(12)** When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1-hour after the initiation of the intervention by a physician or other licensed independent practitioner; or registered nurse or physician assistant who has been trained in accordance with the requirements specified in paragraph (f) of this section.
- A0182 **CFR 482.13(e)(14)** If the face-to-face evaluation specified in paragraph (e)(12) of this section is conducted by a trained registered nurse or physician assistant, the trained registered nurse or physician assistant must consult the attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §482.12(c) as soon as possible after the completion of the 1-hour face-to-face evaluation.
- A0183 **CFR 482.13(e)(15)** All requirements specified under this paragraph are applicable to the simultaneous use of restraint and seclusion. Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored face-to-face by an assigned, trained staff member; or by trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient.
- A0184 **CFR 482.13(e)(16)** When restraint or seclusion is used, there must be documentation in the patient's medical record of the 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior.
- A0185 **CFR 482.13(e)(16)** [When restraint or seclusion is used, there must be documentation in the patient's medical record of] a description of the patient's behavior and the intervention used.
- A0187 **CFR 482.13(e)(16)** [When restraint or seclusion is used, there must be documentation in the patient's medical record of] the patient's condition or symptom(s) that warranted the use of the restraint or seclusion.
- A0188 **CFR 482.13(e)(16)** [When restraint or seclusion is used, there must be documentation in the patient's medical record of] the patient's response to the intervention(s) used, including the rationale for continued use of the intervention.
- A0205 **CFR 482.13(f)(2)(vi)** [The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least] monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation.
- A0214 **CFR 482.13(g)** Hospitals must report deaths associated with the use of seclusion or restraint.

A0215 **CFR 482.13(g)(1)(i)** Hospitals must report the following information to CMS: Each death that occurs while a patient is in restraint or seclusion.

A0216 **CFR 482.13(g)(1)(ii)** Hospitals must report the following information to CMS: Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

A0217 **CFR 482.13(g)(1)(iii)** Hospitals must report the following information to CMS: Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation.

A0221 **CFR 482.13(g)(2)** Each death referenced in this paragraph must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death.

A0222 **CFR 482.13(g)(3)** Staff must document in the patient's medical record the date and time the death was reported to CMS.

A0263 **CFR 482.21** The hospital must develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program.

The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.

The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.

A0264 **CFR 482.21(a)** Standard: Program Scope

The hospital must ensure that specific program requirements are met.

A0267 **CFR 482.21(a)(2)** The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital services and operations.

A0273 **CFR 482.21(b)** Standard: Program Data

The hospital must ensure that specific program data requirements are met.

A0277 **CFR 482.21(b)(3)** The frequency and detail of data collection must be specified by the hospital's governing body.

A0309 **CFR 482.21(e)** The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring that specific QAPI program requirements are met.

A0314 **CFR 482.21(e)(3)** The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and

administrative officials are responsible and accountable for ensuring that clear expectations for safety are established

A0340 **CFR 482.22(a)(1)** The medical staff must periodically conduct appraisals of its members.

A0358 **CFR 482.22(c)(5)** The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must include a requirement that a medical history and physical examination be completed no more than 30 days before or 24 hours after admission for each patient by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified individual in accordance with State law and hospital policy. The medical history and physical examination must be placed in the patient's medical record within 24 hours after admission. When the medical history and physical examination are completed within 30 days before admission, the hospital must ensure that an updated medical record entry documenting an examination for any changes in the patient's condition is completed. This updated examination must be completed and documented in the patient's medical record within 24 hours after admission.

A0385 **CFR 482.23** The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.

A0392 **CFR 482.23(b)** The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.

A0395 **CFR 482.23(b)(3)** A registered nurse must supervise and evaluate the nursing care for each patient.

A0396 **CFR 482.23(b)(4)** The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient.

A0398 **CFR 482.23(b)(6)** Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing services.

A0404 **CFR 482.23(c)** Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice.

A0405 **CFR 482.23(c)(1)** All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

A0409 **CFR 482.23(c)(3)** Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures. If blood transfusions and intravenous medications are administered by personnel other than doctors of medicine or osteopathy, the personnel must have special training for this duty.

A0438 **CFR 482.24(b)** The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.



- A0441 **CFR 482.24(b)(3)** The hospital must have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals.
- A0442 **CFR 482.24(b)(3)** [Information from or copies of records may be released only to authorized individuals,] and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records.
- A0450 **CFR 482.24(c)(1)** All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.
- A0454 **CFR 482.24(c)(2)** (i) All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner, except as noted in paragraph (c)(1)(ii) of this section. (ii) For the 5 year period following January 26, 2007, all orders, including verbal orders, must be dated, timed, and authenticated by the ordering practitioner or another practitioner who is responsible for the care of the patient as specified under §482.12(c) and authorized to write orders by hospital policy in accordance with State law.
- A0467 **CFR 482.24(c)(2)(vi)** [All records must document the following, as appropriate:] All practitioner's orders, nursing notes, reports of treatment, medication records, radiology and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.
- A0469 **CFR 482.24(c)(2)(viii)** [All records must document the following, as appropriate:] Final diagnosis with completion of medical records within 30 days following discharge or outpatient care.
- A0502 **CFR 482.25(b)(2)(i)** All drugs and biologicals must be kept in a secure area, and locked when appropriate.
- A0504 **CFR 482.25(b)(2)(iii)** Only authorized personnel may have access to locked areas.
- A0505 **CFR 482.25(b)(3)** Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.
- A0546 **CFR 482.26(c)(1)** A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiological tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.
- A0553 **CFR 482.26(d)** Records of radiologic services must be maintained.
- A0592 **CFR 482.27(c)** Potentially HIV infectious blood and blood products are prior collections from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to the human immunodeficiency virus (HIV) on a later donation, and the FDA-licensed, more specific test or other follow up testing recommended or required by FDA is positive and the timing of seroconversion cannot be precisely estimated.

Services furnished by an outside blood bank. If a hospital regularly uses the services of an outside blood bank, it must have an agreement with the blood bank that governs the procurement, transfer, and availability of blood and blood products. The agreement must require that the blood bank promptly notify the hospital if it supplied blood and blood products collected from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to HIV on a later donation; and the results of the FDA-licensed, more specific test or other follow up testing recommended or required by FDA completed within 30 calendar days

If a hospital regularly uses the services of an outside blood bank, it must have an agreement with the blood bank that governs the procurement, transfer, and availability of blood and blood products. The agreement must require that the blood bank promptly notify the hospital of the following:

If it supplied blood and blood products collected from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to HIV on a later donation, and;

The results of the FDA-licensed, more specific test or other follow up testing recommended or required by FDA completed within 30 calendar days after the donor's repeatedly reactive screening test. (Regulations concerning FDA licensing and approval of tests are set forth at 21 CFR 610.45-et seq.)

If the blood bank notifies the hospital of the repeatedly reactive HIV screening test results as required by paragraph (c)(2)(i) of this section, the hospital must determine the disposition of the blood or blood product and quarantine all blood and blood products from previous donations in inventory.

If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other follow up testing recommended by FDA is negative, absent other informative test results, the hospital may release the blood and blood products from quarantine.

If the blood bank notifies the hospital that the results of the FDA-licensed, more specific test or other follow up testing recommended by FDA is positive, the hospital must dispose of the blood and blood products in accordance with 21 CFR 606.40 and notify patients in accordance with paragraph (c)(4) of this section.

If the hospital has administered potentially HIV infectious blood or blood products (either directly through its own blood bank or under an agreement described in paragraph (c)(2) of this section) or released such blood or blood products to another entity or appropriate individual, the hospital must take the following actions:

- o Promptly make at least three attempts to notify the patient's attending physician (that is, the physician of record) or the physician who ordered the blood or blood products that potentially HIV infectious blood or blood products were transfused to the patient.
- o Ask the physician to immediately notify the patient, or other individual as permitted under paragraph (c)(8) of this section, of the need for HIV testing and counseling.
- o If the physician is unavailable, declines to make the notification, or later informs the hospital that he or she was unable to notify the patient, promptly make at least three attempts to notify the patient, or other individual as permitted under paragraph (c)(8) of this section, of the need for HIV testing and counseling
- o Document in the patient's medical record the notification or attempts to give the required notification.

The notification effort begins when the blood bank notifies the hospital that it received potentially HIV infectious blood and blood products and continues for 8 weeks unless:

- The patient is located and notified; or
- The hospital is unable to locate the patient and documents in the patient's medical record the extenuating circumstances beyond the hospital's control that caused the notification time frame to exceed 8 weeks.

The notification given under paragraphs (c)(4)(ii) and (iii) of this section must include the following information:

- o A basic explanation of the need for HIV testing and counseling.
- o Enough oral or written information so that the transfused patient can make an informed decision about whether to obtain HIV testing and counseling.
- o A list of programs or places where the patient can obtain HIV testing and counseling, including any requirements or restrictions the program may impose.

The hospital must establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for confidentiality and medical records.

If the patient has been adjudged incompetent by a State court, the physician or hospital must notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or hospital must notify the patient or his or her legal representative or relative. If the patient is deceased, the physician or hospital must continue the notification process and inform the deceased patient's legal representative or relative.

A0620 **CFR 482.28(a)(1)** The hospital must have a full-time employee who serves as director of the food and dietetic services; is responsible for daily management of the dietary services; and is qualified by experience or training.

A0621 **CFR 482.28(a)(2)** There must be a qualified dietitian, full-time, part-time, or on a consultant basis.

A0622 **CFR 482.28(a)(c)** There must be administrative and technical personnel competent in their respective duties.

A0629 **CFR 482.28(b)(1)** Therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the patients.

A0630 **CFR 482.28(b)(2)** Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the patients.

A0631 **CFR 482.28(b)(3)** A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.

A0701 **CFR 482.41(a)** The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.

A0713 **CFR 482.41(b)(6)** The hospital must have procedures for the proper routine storage and prompt disposal of trash.

A0724 **CFR 482.41(c)(2)** Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

A0726 **CFR 482.41(c)(4)** There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

A0749 **CFR 482.42(a)(1)** The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

A0887 **CFR 482.45(a)(2)** [The hospital must have and implement written protocols that:] Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement.

A0889 **CFR 482.45(a)(3)** The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation.

A0891 **CFR 482.45(a)(5)** [The hospital must have and implement written protocols that:] Ensure that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues.

A0959 **CFR 482.51(b)(6)** An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.

A1077 **CFR 482.54(e)** Outpatient services must be appropriately organized and integrated with inpatient services.

A1079 **CFR 482.54(b)** The hospital must assign an individual to be responsible for outpatient services; and have appropriate professional and nonprofessional personnel available.

A1132 **CFR 482.56(b)** Services must be furnished in accordance with a written plan of treatment. Services must be given in accordance with orders of practitioners who are authorized by the medical staff to order the services, and the orders must be incorporated in the patient's record.

A1510 **CFR 482.66(b)(1)** The facility must inform each resident who is entitled to Medicaid benefits, in writing, at the time of admission to the nursing facility or, when the resident becomes eligible for Medicaid of the items and services that are included in nursing facility services under the State plan and for which the resident may not be charged; those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and inform each resident when changes are made to the items and services specified in paragraphs (5)(i)(A) and (B) of this section.

The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare or by the facility's per diem rate.

A1516 **CFR 482.66(b)(1)** The resident has the right to privacy in written communications, including the right to send and promptly receive mail that is unopened; and have access to stationery, postage, and writing implements at the resident's own expense.

A1518 **CFR 482.66(b)(1)** The resident has the right to retain and use personal possessions, including some furnishings, and appropriate clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.

A1519 **CFR 482.66(b)(1)** The resident has the right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.

A1525 **CFR 482.66(b)** Before a facility transfers or discharges a resident, the facility must notify the resident and, if known, a family member or legal representative of the resident of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand; record the reasons in the resident's clinical record; and include in the notice the items described in paragraph (a)(6) of this section.

A1537 **CFR 482.66(b)(4)** The facility must provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident.

The activities program must be directed by a qualified professional who is a qualified therapeutic recreation specialist or an activities professional who is licensed or registered, if applicable, by the State in which practicing; and is eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or has 2 years of experience in a social or recreational program within the last 5 years, 1 of which was full-time in a patient activities program in a health care setting; or is a qualified occupational therapist or occupational therapy assistant; or has completed a training course approved by the State.

A2400 **CFR 489.20(l)** The provider agrees, in the case of a hospital as defined in §489.24(b), to comply with §489.24.

A2402 **CFR 489.20(q)** The provider agrees, in the case of a hospital as defined in §489.24(b), to post conspicuously in any emergency department or in a place or places likely to be noticed by all individuals entering the emergency department, as well as those individuals waiting for examination and treatment in areas other than traditional emergency departments (that is, entrance, admitting area, waiting room, treatment area) a sign (in a form specified by the Secretary) specifying the rights of individuals under section 1867 of the Act with respect to examination and treatment for emergency medical conditions and women in labor; and to post conspicuously (in a form specified by the Secretary) information indicating whether or not the hospital or rural primary care hospital (e.g., critical access hospital) participates in the Medicaid program under a State plan approved under Title XIX.

A2406 **CFR 489.(r) and 489.24(c)** In the case of a hospital that has an emergency department, if an individual (whether or not eligible for Medicare benefits and regardless of ability to pay) "comes to the emergency department", as defined in paragraph (b) of this section, the hospital must provide an appropriate medical screening examination within the capability of the hospital's emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition exists. The examination must be conducted by an individual(s) who is determined qualified by hospital bylaws or rules and regulations and who meets the requirements of §482.55 of this chapter concerning emergency services personnel and direction.

If an emergency medical condition is determined to exist, the hospital must provide any necessary stabilizing treatment, as defined in paragraph (d) of this section, or an appropriate transfer as defined in paragraph (e) of this section. If the hospital admits the individual as an inpatient for further treatment, the hospital's obligation under this section ends, as specified in paragraph (d)(2) of this section.

Sanctions under this section for inappropriate transfer during a national emergency do not apply to a hospital with a dedicated emergency department located in an emergency area, as specified in section 1135(g)(1) of the Act.

If an individual comes to a hospital's dedicated emergency department and a request is made on his or her behalf for examination or treatment for a medical condition, but the nature of the request makes it clear that the medical condition is not of an emergency nature, the hospital is required only to perform such screening as would be appropriate for any individual presenting in that manner, to determine that the individual does not have an emergency medical condition.

## Federal Certification Critical Access Hospitals:

### *(Multiple versions of "C" tags in effect)*

C0195 **CFR 485.616(b)** Each CAH that is a member of a rural health network shall have an agreement with respect to credentialing and quality assurance with at least -

- (1) one hospital that is a member of the network;
- (2) one QIO or equivalent entity; or
- (3) one other appropriate and qualified entity identified in the State rural health care plan.

C0201 **CFR 485.618(a)** Emergency services are available on a 24-hours a day basis.

C0202 **CFR 485.618(b)** Equipment, supplies and medication used in treating emergency cases are kept at the CAH and are readily available for treating emergency cases. The items available must include the following:

C0203 **CFR 485.618(b)(1)** [The items available must include the following:]

(1) Drugs and biologicals commonly used in life-saving procedures, including analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarrhythmics, cardiac glycosides, antihypertensives, diuretics, and electrolytes and replacement solutions.

C0205 **CFR 485.618(c)(1)** The facility provides, either directly or under arrangement, the following:

(1) services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hours a day basis

C0207 **CFR 485.618(d)** (1) Except as specified in paragraph (d)(3) of this section, there must be a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care, on call and immediately available by telephone or radio contact, and available on site within the following timeframes:

(i) Within 30 minutes, on a 24-hour a day basis, if the CAH is located in an area other than an area described in paragraph (d)(1)(ii) of this section; or

(ii) within 60 minutes, on a 24-hour a day basis, if all of the following requirements are met:

(A) The CAH is located in an area designated as a frontier area (that is, an area with fewer than six residents per square mile based on the latest population data published by the Bureau of the Census) or in an area that meets criteria for a remote location adopted by the State in its rural health care plan, and approved by CMS, under section 1820(b) of the Act.

(B) The State has determined, under criteria in its rural health care plan, that allowing an emergency response time longer than 30 minutes is the only feasible method of providing emergency care to residents of the area served by the CAH.

(C) The State maintains documentation showing that the response time of up to 60 minutes at a particular CAH it designates is justified because other available alternatives would increase the time needed to stabilize a patient in an emergency.

(2) A registered nurse with training and experience in emergency care can be utilized to conduct specific medical screening examinations only if

(i) The registered nurse is on site and immediately available at the CAH when a patient requires medical care; and

(ii) The nature of the patient's request for medical care is within the scope of practice of a registered nurse and consistent with applicable State laws and the CAH's bylaws or rules and regulations.

(3)A registered nurse satisfies the personnel requirement specified in paragraph (d)(1) of this section for a temporary period if --

(i) The CAH has no greater than 10 beds;

(ii) The CAH is located in an area designated as a frontier area or remote location as described in paragraph (d)(1)(ii)(A) of this section;

(iii) The State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation on the issue of using RNs on a temporary basis as part of their State rural health care plan with the State Boards of Medicine and Nursing, and in accordance with State law, requesting that a registered nurse with training and experience in emergency care be included in the list of personnel specified in paragraph (d)(1) of this section. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of emergency services in the States. The letter from the Governor must also describe the circumstances and duration of the temporary request to include the registered nurses on the list of personnel specified in paragraph (d)(1) of this section.

(iv) Once a Governor submits a letter, as specified in paragraph (d)(3)(iii) of this section, a CAH must submit documentation to the State survey agency demonstrating that it has been unable, due to the shortage of such personnel in the area, to provide adequate coverage as specified in this paragraph (d).

(4)The request, as specified in paragraph (d)(3)(iii) of this section, and the withdrawal of the request, may be submitted to us at any time, and are effective upon submission.

C0211 **CFR 485.620(a)** Except as permitted for CAHs having distinct part units under §485.647, the CAH maintains no more than 25 inpatient beds after January 1, 2004, that can be used for either inpatient or swing-bed services.

C0222 **CFR 485.623(b)(1)** The CAH has housekeeping and preventive maintenance programs to ensure that-

(1) all essential mechanical, electrical, and patient care equipment is maintained in safe operating condition;

C0223 **CFR 485.623(b)(2)** [The CAH has housekeeping and preventive maintenance programs to ensure that--]

(2) there is proper routine storage and prompt disposal of trash;

C0224 **CFR 485.623(b)(3)** [The CAH has housekeeping and preventive maintenance programs to ensure that--]

(3) drugs and biologicals are appropriately stored;

C0225 **CFR 485.623(b)(4) [3.00]** The CAH has housekeeping and preventive maintenance programs to ensure that the premises are clean and orderly.

**[4.02]** [The CAH has housekeeping and preventive maintenance programs to ensure that-

(4) the premises are clean and orderly;

C0226 **CFR 485.623(b)(5)** [The CAH has housekeeping and preventive programs to ensure that-

(5) there is proper ventilation, lighting, and temperature control in all pharmaceutical, patient care, and food preparation areas.

C0229 **CFR 485.623(c)(3)** [The CAH assures the safety of patients in non-medical emergencies by--  
]

(3) providing for an emergency fuel and water supply; and.

C0230 **CFR 485.623(c)(4)** [The CAH assures the safety of patients in non-medical emergencies by--  
]

(4) taking other appropriate measures that are consistent with the particular conditions of the area in which the CAH is located.

C0240 **CFR 485.627** Organizational Structure

C0241 **CFR 485.627(a)** The CAH has a governing body or an individual that assumes full legal responsibility for determining, implementing, and monitoring policies governing the CAH's total operation and for ensuring that those policies are administered so as to provide quality health care in a safe environment.

C0244 **CFR 485.627(b)(3)** [The CAH discloses the name and addresses of--]

(3) the person responsible for medical direction

C0250 **CFR 485.631** Staffing and Staff Responsibilities

C0252 **CFR 485.631(a)(2)** Any ancillary personnel are supervised by the professional staff.

C0258 **CFR 485.631(b)(1)(ii)** [The doctor of medicine or osteopathy-]

(ii) in conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the CAH's written policies governing the services it furnishes;

C0259 **CFR 485.631(b)(1)(iii)** [The doctor of medicine or osteopathy-]

(iii) in conjunction with the physician assistant and/or nurse practitioner members, periodically reviews the CAH's patient records, provides medical orders, and provides medical care services to the patients of the CAH; [and]

C0260 **CFR 485.631(b)(1)(iv)** [The doctor of medicine or osteopathy-]

(iv) Periodically reviews and signs the records of all inpatients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants.

C0263 **CFR 485.631(b)(2)** A doctor of medicine or osteopathy is present for sufficient periods of time, at least once in every 2 week period (except in extraordinary circumstances) to provide the medical direction, medical care services, consultation, and supervision described in this paragraph, and is available through direct radio or telephone communication for consultation, assistance with medical emergencies, or patient referral. The extraordinary circumstances are documented in the records of the CAH. A site visit is not required if no patients have been treated since the last site visit.

C0264 **CFR 485.631(c)** Physician Assistant, Nurse Practitioner, or Clinical Nurse Specialist Responsibilities



C0270 **CFR 485.635** Provision of Services

C0271 **CFR 485.635(a)(1)** The CAH's health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law.

C0272 **CFR 485.635(a)(2)** The policies are developed with the advice of a group of professional personnel that includes one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of §485.631(a)(1); at least one member is not a member of the CAH staff.

C0273 **CFR 485.635(a)(3)(i)** The policies include the following:

(i) a description of the services the CAH furnishes directly and those furnished through agreement or arrangement.

C0274 **CFR 485.635(a)(3)(ii)** [The policies include the following:]

(ii) policies and procedures for emergency medical services

C0275 **CFR 485.635(a)(3)(iii)** [The policies include the following:]

(iii) guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the CAH.

C0276 **CFR 485.635(a)(3)(iv)** [The policies include the following:]

(iv) rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.

C0278 **CFR 485.635(a)(vi)** [The policies include the following:]

(vi) a system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel.

C0279 **CFR 485.635(a)(3)(vii)** [The policies include the following:]

(vii) If the CAH furnishes inpatient services, procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of §485.25(i) is met with respect to inpatients receiving posthospital SNF care.

C0280 **CFR 485.635(a)(4)** These policies are reviewed at least annually by the group of professional personnel required under paragraph (a)(2) of this section, and reviewed as necessary by the CAH.

C0281 **CFR 485.635(b)(1)** General The CAH staff furnishes, as direct services, those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These direct services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.

C0282 **CFR 485.635(b)(2)** Laboratory services. The CAH provides, as direct services, basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). (See the laboratory requirements specified in part 493 of this chapter.) The services provided include:  
(i) Chemical examination of urine by stick or tablet method or both (including urine ketones);  
(ii) Hemoglobin or hematocrit;  
(iii) Blood glucose;  
(iv) Examination of stool specimens for occult blood;  
(v) Pregnancy tests; and  
(vi) Primary culturing for transmittal to a certified laboratory.

C0283 **CFR 485.635(b)(3)** Radiology services. Radiology services furnished at the CAH are provided as direct services by staff qualified under State law, and do not expose CAH patients or staff to radiation hazards.

C0291 **CFR 485.635(c)(3)** The CAH maintains a list of all services furnished under arrangements or agreements. The list describes the nature and scope of the services provided.

C0292 **CFR 485.635(c)(4)(i)** The person principally responsible for the operation of the CAH under §485.627(b)(2) of this chapter is also responsible for the following:

(i) services furnished in the CAH whether or not they are furnished under arrangements or agreements.

C0294 **CFR 485.635(d)** Nursing services must meet the needs of patients.

C0298 **CFR 485.635(d)(4)** A nursing care plan must be developed and kept current for each inpatient.

C0301 **CFR 485.638(a)(1)** The CAH maintains a clinical records system in accordance with written policies and procedures.

C0302 **CFR 485.633(a)(2)** The records are legible, complete, accurately documented, readily accessible, and systematically organized.

C0304 **CFR 485.638(a)(4)(i)** For each patient receiving health care services, the CAH maintains a record that includes, as applicable-

(i) identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

C0305 **CFR 485.638(a)(4)(ii)** [For each patient receiving health care services, the CAH maintains a record that includes, as applicable-]

(ii) reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings;

C0306 **CFR 485.638(a)(4)(iii)** For each patient receiving health care services, the CAH maintains a record that includes, as applicable-]

(iii) all orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary

to monitor the patient's progress, such as temperature graphics and progress notes describing the patient's response to treatments; [and]

C0307 **CFR 485.638(a)(4)(iv) [3.00]** For each patient receiving health care services, the CAH maintains a record that includes, as applicable, dated signatures of the doctor of medicine or osteopathy or other health care professional.

**[4.02]** [For each patient receiving health care services, the CAH maintains a record that includes, as applicable-]

(iv) dated signatures of the doctor of medicine or osteopathy or other health care professional.

C0308 **CFR 485.638(b)(1)** The CAH maintains the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use.

C0309 **CFR 485.638(b)(2)** Written policies and procedures govern the use and removal of records from the CAH and the conditions for the release of information.

C0320 **CFR 485.639** Surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the CAH in accordance with the designation requirements under paragraph (a) of this section.

C0322 **CFR 485.639(b)** (1) A qualified practitioner, as specified in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed.  
(2) A qualified practitioner, as specified in paragraph (c) of this section, must examine each patient before surgery to evaluate the risk of anesthesia.  
(3) Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (c) of this section.

C0323 **CFR 485.639(c)(1)** The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope of practice laws.

(1) Anesthesia must be administered by only -

- (i) a qualified anesthesiologist;
- (ii) a doctor of medicine or osteopathy other than an anesthesiologist, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;
- (iii) a doctor of dental surgery or dental medicine;
- (iv) a doctor of podiatric medicine;
- (v) a certified registered nurse anesthetist (CRNA), as defined in Sec. 410.69(b) of this chapter;
- (vi) an anesthesiologist's assistant, as defined in Sec. 410.69(b) of this chapter; or
- (vii) a supervised trainee in an approved educational program, as described in §§413.85 or 413.86 of this chapter.

C0330 **CFR 485.641 [3.00]** The CAH must ensure that specific periodic evaluation and quality assurance review requirements are met.

**[4.02]** Periodic Evaluation and Quality Assurance Review

C0331 **CFR 485.641(a)(1)** The CAH carries out or arranges for a periodic evaluation of its total program. The evaluation is done at least once a year and includes review of—

C0332 **CFR 485.641(a)(1)(i)** [The evaluation is done at least once a year and includes review of--]

(i) the utilization of CAH services, including at least the number of patients served and the volume of services.

C0333 **CFR 485.641(a)(1)(ii)** [3.00] The evaluation includes review of a representative sample of both active and closed clinical records.

**[4.02]** [The evaluation is done at least once a year and includes review of--]

(ii) a representative sample of both active and closed clinical records.

C0334 **CFR 485.641(a)(1)(iii)** [The evaluation is done at least once a year and includes review of--]

(i) the CAH's health care policies.

C0335 **CFR 485.641(a)(2)** The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and any changes are needed.

C0336 **CFR 485.641(b)** [3.00] The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes.

**[4.02]** The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. The program requires that -

C0337 **CFR 485.641(b)(1)** The quality assurance program requires that all patient care services and other services affecting patient health and safety are evaluated.

C0338 **CFR 485.641(b)(2)** [The program requires that--] nosocomial infections and medication therapy are evaluated;

C0339 **CFR 485.641(b)(3)** [The program requires that--] the quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the CAH are evaluated by a member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH;

C0340 **CFR 485.641(b)(4)** [The program requires that--] the quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the CAH are evaluated by-

(i) one hospital that is a member of the network, when applicable;

(ii) one QIO or equivalent entity; or

(iii) one other appropriate and qualified entity identified in the State rural health care plan; and

C0345 **CFR 485.643(a)** [The CAH must have and implement written protocols that:] incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the CAH. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose;

C0360 **CFR 485.645(d)** The CAH is substantially in compliance with the following SNF requirements contained in subpart B of part 483 of this chapter:

- (1) Resident rights (§483.10(b)(3) through (b)(6), (d), (e), (h),(i), (j)(1)(vii) and (viii), (1), and (m) of this chapter).
- (2) Admission, transfer, and discharge rights (§483.12(a) of this chapter).
- (3) Resident behavior and facility practices (§483.13 of this chapter).
- (4) Patient activities (§483.15(f) of this chapter), except that the services may be directed either by a qualified professional meeting the requirements of §483.15(f)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy.
- (5) Social services (§483.15(g) of this chapter).
- (6) Comprehensive assessment, comprehensive care plan, and discharge planning (§483.20(b), (k), and (l) of this chapter, except that the CAH is not required to use the resident assessment instrument (RAI) specified by the State that is required under §483.20(b), or to comply with the requirements for frequency, scope, and number of assessments prescribed in §413.343(b) of this chapter).
- (7) Specialized rehabilitative services (§483.45 of this chapter).
- (8) Dental services (§483.55 of this chapter).
- (9) Nutrition (§483.25(i) of this chapter).

C0364 **CFR 485.645(d)(1)** The resident has the right to choose a personal attending physician.

C0366 **CFR 485. 645(d)(1)** The resident has a right, unless adjudged incompetent or otherwise found to be incapacitated under the laws of the State, to participate in planning care and treatment or changes in care and treatment.

C0368 **CFR 485. 645(d)(1)** The resident has the right to refuse to perform services for the facility or perform services for the facility, if he or she chooses, when the facility has documented the need or desire for work in the plan of care; the plan specifies the nature of the services performed and whether the services are voluntary or paid; compensation for paid services is at or above prevailing rates; and the resident agrees to the work arrangement described in the plan of care.

C0369 **CFR 485. 645(d)(1)** The resident has the right to privacy in written communications, including the right to send and promptly receive mail that is unopened, and have access to stationery, postage, and writing implements at the resident's own expense.

C0370 **CFR 485. 645(d)(1)** The resident has the right and the facility must provide immediate access to any resident by any representative of the Secretary; subject to the resident's right to deny or withdraw consent at any time, immediate family or other relatives of the resident; and, subject to reasonable restrictions and the resident's right to deny or withdraw consent at any time, others who are visiting with the consent of the resident.

C0371 **CFR 485. 645(d)(1)** The resident has the right to retain and use personal possessions, including some furnishings, and appropriate clothing, as space permits, unless to do so would infringe upon the rights and safety of other residents.

C0372 **CFR 485. 645(d)(1)** The resident has the right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.

C0373 **CFR 485. 645(d)(1)** The resident has the right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.

C0374 **CFR 485. 645(d)(2)** The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless the transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility; or the transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility; or the safety of individuals in the facility is endangered; or the health of individuals in the facility would otherwise be endangered; or the resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility.

For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge a resident only allowable charges under Medicaid; or the facility ceases to operate.

C0379 **CFR 485. 645(d)(2)** The written notice specified in paragraph (a)(4) of this section must include the following.

- o The reason for transfer or discharge;
- o The effective date of transfer or discharge;
- o The location to which the resident is transferred or discharged;
- o A statement that the resident has the right to appeal the action to the State; and
- o The name, address and telephone number of the State long term care ombudsman.
- o For nursing facility residents with developmental disabilities, the mailing address and telephone number of the agency responsible for the protection and advocacy of developmentally disabled individuals established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act.
- o For nursing facility residents who are mentally ill, the mailing address and telephone number of the agency responsible for the protection and advocacy for mentally ill individuals established under the Protection and Advocacy for Mentally Ill Individuals Act.

C0381 **CFR 485. 645(d)(3)** The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms.

C0385 **CFR 485.645(d)(4) [3.00]** A facility must care for its residents in a manner and in an environment that promotes maintenance or enhancement of each resident's quality of life. The facility must provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident.

The activities program must be directed by a qualified professional who--

- (i) Is a qualified therapeutic recreation specialist or an activities professional who--
  - (A) Is licensed or registered, if applicable, by the State in which practicing; and
  - (B) Is eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or
- (ii) Has 2 years of experience in a social or recreational program within the last 5 years, 1 of which was full-time in a patient activities program in a health care setting; or
- (iii) Is a qualified occupational therapist or occupational therapy assistant; or
- (iv) Has completed a training course approved by the State.

**[4.02]** A facility must care for its residents in a manner and in an environment that promotes maintenance or enhancement of each resident's quality of life. The facility must provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident.

The activities program must be directed by a qualified professional who is a qualified therapeutic recreation specialist or an activities professional who--

- o Is licensed or registered, if applicable, by the State in which practicing; and

- o Is eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or
- o Has 2 years of experience in a social or recreational program within the last 5 years, 1 of which was full-time in a patient activities program in a health care setting; or
- o Is a qualified occupational therapist or occupational therapy assistant; or
- o Has completed a training course approved by the State.

C0386           **CFR 485.645(d)(5)** The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

A facility with more than 120 beds must employ a qualified social worker on a full-time basis.

A qualified social worker is an individual with a bachelor's degree in social work or a bachelor's degree in a human services field including but not limited to sociology, special education, rehabilitation counseling, and psychology; and one year of supervised social work experience in a health care setting working directly with individuals.

C0395           **CFR 485. 645(d)(6)** The facility must develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, mental and psychosocial needs that are identified in the comprehensive assessment.

The care plan must describe the services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under §483.25; and any services that would otherwise be required under §483.25 but are not provided due to the resident's exercise of rights under §483.10, including the right to refuse treatment under §483.10(b)(4).

C0396           **CFR 485. 645(d)(6)** A comprehensive care plan must be developed within 7 days after the completion of the comprehensive assessment; prepared by an interdisciplinary team that includes the attending physician, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident's needs, and, to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative; and periodically reviewed and revised by a team of qualified persons after each assessment.

C0399           **CFR 485.645(d)(6)** When the facility anticipates discharge a resident must have a discharge summary that includes a recapitulation of the resident's stay; a final summary of the resident's status to include items in paragraph (b)(2) of this section, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or legal representative; and a post-discharge plan of care that is developed with the participation of the resident and his or her family, which will assist the resident to adjust to his or her new living environment.

C0404           **CFR 485.645(d)(8)** The facility must assist residents in obtaining routine and 24-hour emergency dental care.

C2400           **CFR 489.20(l)** [The provider agrees,] in the case of a hospital as defined in §489.24(b), to comply with §489.24.

C2402           **CFR 489.20(q)** [The provider agrees,] in the case of a hospital as defined in §489.24(b), to post conspicuously in any emergency department or in a place or places likely to be noticed by all individuals entering the emergency department, as well as those individuals waiting for examination and treatment in areas other than traditional emergency departments (that is, entrance, admitting area, waiting room, treatment area) a sign (in a form specified by the Secretary) specifying the rights of individuals under section 1867 of the Act with respect to examination and treatment for emergency medical conditions and

women in labor; and to post conspicuously (in a form specified by the Secretary) information indicating whether or not the hospital or rural primary care hospital (e.g., critical access hospital) participates in the Medicaid program under a State plan approved under Title XIX.

C2405 **CFR 489.20(r)(3)** [The provider agrees,] in the case of a hospital as defined in §489.24(b) (including both the transferring and receiving hospitals), to maintain a central log on each individual who comes to the emergency department, as defined in §489.24(b), seeking assistance and whether he or she refused treatment, was refused treatment, or whether he or she was transferred, admitted and treated, stabilized and transferred, or discharged.

§489.24 The provisions of this regulation apply to all hospitals that participate in Medicare and provide emergency services.

C2407 **CFR 489.24(d)(1-3)** (1) General. Subject to the provisions of paragraph (d)(2) of this section, if any individual (whether or not eligible for Medicare benefits) comes to a hospital and the hospital determines that the individual has an emergency medical condition, the hospital must provide either-

- (i) within the capabilities of the staff and facilities available at the hospital, for further medical examination and treatment as required to stabilize the medical condition.
- (ii) For transfer of the individual to another medical facility in accordance with paragraph (e) of this section.

(2) Exception: Application to inpatients.

(i) If a hospital has screened an individual under paragraph (a) of this section and found the individual to have an emergency medical condition, and admits that individual as an inpatient in good faith in order to stabilize the emergency medical condition, the hospital has satisfied its special responsibilities under this section with respect to that individual

(ii) This section is not applicable to an inpatient who was admitted for elective (nonemergency) diagnosis or treatment.

(iii) A hospital is required by the conditions of participation for hospitals under Part 482 of this chapter to provide care to its inpatients in accordance with those conditions of participation.

(3) Refusal to consent to treatment. A hospital meets the requirements of paragraph (d)(1)(i) of this section with respect to an individual if the hospital offers the individual the further medical examination and treatment described in that paragraph and informs the individual (or a person acting on the individual's behalf) of the risks and benefits to the individual of the examination and treatment, but the individual (or a person acting on the individual's behalf) does not consent to the examination or treatment. The medical record must contain a description of the examination, treatment, or both if applicable, that was refused by or on behalf of the individual. The hospital must take all reasonable steps to secure the individual's written informed refusal (or that of the person acting on his or her behalf). The written document should indicate that the person has been informed of the risks and benefits of the examination or treatment, or both.

C2409 **CFR 489.24(e)(1-2)** (1) General

If an individual at a hospital has an emergency medical condition that has not been stabilized (as defined in paragraph (b) of this section), the hospital may not transfer the individual unless -

(i) The transfer is an appropriate transfer (within the meaning of paragraph (e)(2) of this section); and

(ii)(A) The individual (or a legally responsible person acting on the individual's behalf) requests the transfer, after being informed of the hospital's obligations under this section and of the risk of transfer.

The request must be in writing and indicate the reasons for the request as well as indicate that he or she is aware of the risks and benefits of the transfer.

(B) A physician (within the meaning of section 1861(r)(1) of the Act) has signed a certification that, based upon the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the



individual or, in the case of a woman in labor, to the woman or the unborn child, from being transferred. The certification must contain a summary of the risks and benefits upon which it is based; or

(C) If a physician is not physically present in the emergency department at the time an individual is transferred, a qualified medical person (as determined by the hospital in its bylaws or rules and regulations) has signed a certification described in paragraph (e)(1)(ii)(B) of this section after a physician (as defined in section 1861(r)(1) of the Act) in consultation with the qualified medical person, agrees with the certification and subsequently countersigns the certification. The certification must contain a summary of the risks and benefits upon which it is based.

(2) A transfer to another medical facility will be appropriate only in those cases in which -

(i) The transferring hospital provides medical treatment within its capacity that minimizes the risks to the individual's health and, in the case of a woman in labor, the health of the unborn child;

(ii) The receiving facility

(A) Has available space and qualified personnel for the treatment of the individual; and

(B) Has agreed to accept transfer of the individual and to provide appropriate medical treatment.

(iii) The transferring hospital sends to the receiving facility all medical records (or copies thereof) related to the emergency condition which the individual has presented that are available at the time of the transfer, including available history, records related to the individual's emergency medical condition, observations of signs or symptoms, preliminary diagnosis, results of diagnostic studies or telephone reports of the studies, treatment provided, results of any tests and the informed written consent or certification (or copy thereof) required under paragraph (e)(1)(ii) of this section, and the name and address of any on-call physician (described in paragraph (g) of this section) who has refused or failed to appear within a reasonable time to provide necessary stabilizing treatment. Other records (e.g., test results not yet available or historical records not readily available from the hospital's files) must be sent as soon as practicable after transfer; and

(iv) The transfer is effected through qualified personnel and transportation equipment, as required, including the use of necessary and medically appropriate life support measures during the transfer.

### **State and Federal Certification for Ambulatory Surgical Centers:**

S0500           **KAR 28-34-57(e)** Each record shall be dated and authenticated by the person making the entry. Nursing notes and observations shall be signed and dated by the registered nurse or licensed practical nurse making the entry. Verbal orders by authorized individuals shall be accepted and transcribed only by designated personnel

S0530           **KAR 28-34-58a(a)** Each ambulatory surgical center shall establish and maintain an ongoing infection control program. The program shall be based upon guidelines established by the centers for disease control and the licensing department. . . .

S0535           **KAR 28-34-58a(a)(1)** The program shall include the following:  
(1) Measures for the surveillance, prevention, and control of infections;

S0575           **KAR 28-34-58a(b)** Upon employment, each individual shall have a medical examination consisting of examinations appropriate to the duties of the employee, including a tuberculin skin test. Subsequent medical examinations or health assessments shall be given periodically in accordance with the facility's policies.

S0615 **KAR 28-34-58a(f)** All garbage and waste shall be collected, stored, and disposed of in a manner that does not encourage the transmission of contagious disease. Containers shall be washed and sanitized before being returned to work areas, or the containers may be disposable.

S0620 **KAR 28-34-58a(g)** Staff shall make periodic checks, according to the facility's policies and procedures, throughout the premises to enforce sanitation procedures.

S0640 **KAR 28-34-58a(h)(2)** The accuracy of instruments shall be checked, and surveillance methods, according to the facility's policies and procedures, for checking sterilization procedures shall be employed.

S0720 **KAR 28-34-59a(i)** Policies and procedures. There shall be policies and procedures developed by a pharmacist, and approved by the governing authority, related to the following:

- (1) Storage of drugs;
- (2) security of drugs;
- (3) labeling and preparation of drugs;
- (4) administration of drugs; and
- (5) disposal of drugs.

S0740 **KAR 28-34-59a(m)** Quality assurance. There shall be a mechanism for the ongoing review and evaluation of the quality and scope of radiological, laboratory, and pharmacy services.

S0800 **KAR 28-34-61a(a)** Each ambulatory surgical center shall be designed, constructed, equipped, and maintained to protect the health and safety of patients, staff, and visitors.

Q0002 **CFR 416.40** The ambulatory surgical center must comply with state licensure requirements.

Q0003 **CFR 416.41** The ambulatory surgical center must have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the center's total operation and for ensuring that these policies are administered so as to provide quality health care in a safe environment. When services are provided through a contract with an outside resource, the center must assure that these services are provided in a safe and effective manner.

Q0006 **CFR 416.42(a)** A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Before discharge from the ambulatory surgical center, each patient must be evaluated by a physician for proper anesthesia recovery.

Q0009 **CFR 416.43** The ambulatory surgical center, with the active participation of the medical staff, must conduct an ongoing, comprehensive self-assessment of the quality of care provided, including medical necessity of procedures performed and appropriateness of care, and use findings, when appropriate, in the revision of center policies and consideration of clinical privileges.

Q0011 **CFR 416.44(a)** The ambulatory surgical center must provide a functional and sanitary environment for the provision of surgical services.

Q0034 **CFR 416.49** If the ambulatory surgical center performs laboratory services, it must meet the requirements of Part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of services to perform the referral test in accordance with the requirements of

Part 493 of this chapter. The ASC must have procedures for obtaining radiologic services, from Medicare approved facilities, to meet the needs of patients.

**State Risk Management for Acute Care, Critical Access Hospitals, and Ambulatory Surgical Centers:**

R0800 **KAR 28-52-1(a)** Each medical care facility shall establish a written plan for risk management and patient care quality assessment on a facility-wide basis.

R0801 **KAR 28-52-1(b)** The plan shall be approved and reviewed annually by the facility's governing body.

R0802 **KAR 28-52-1(c)** Findings, conclusions, recommendations, actions taken, and results of actions taken shall be documented and reported through procedures established within the risk management plan.

R0803 **KAR 28-52-1(d)** All patient services including those services provided by outside contractors or consultants shall be periodically reviewed and evaluated in accordance with the plan.

R0805 **KAR 28-52-1(e)(2)** Plan format. Each submitted plan shall include the following:

Section II - a description of the measures used by the facility to minimize the occurrence of reportable incidents and the resulting injuries within the facility;

R0807 **KAR 28-52-1(e)(4)(A)(B)** Plan format. Each submitted plan shall include the following:

Section IV, organization - a description of the organizational elements of the plan including:

- A) Name and address of the facility;
- B) name and title of the facility's risk manager;

R0808 **KAR 28-52-1(e)(4)(C)** Plan format. Each submitted plan shall include the following:

Section IV C) description of involvement and organizational structure of medical staff as related to risk management program, including names and titles of medical staff members involved in investigation and review of reportable incidents;

R0809 **KAR 28-52-1(e)(4)(D)** Plan format. Each submitted plan shall include the following:

Section IV D) organizational chart indicating position of the facility's review committee as defined in K.S.A. 65-65-4923 and L. 1986, Ch. 229, new Section 4(a)(2);

R0811 **KAR 28-52-1(e)(5)** Plan format. Each submitted plan shall include the following:

Section V – a description of the facility's resources allocated to implement the plan.

R0813 **KAR 28-52-1(f)** Plan submittal. On and after November 1, 1986, each medical care facility shall submit the plan to the department at least 60 days prior to the license renewal date. After an initial plan is approved, any amendments to the plan shall be submitted to the department.

R0819 **KSA 65-4923(a)(2)** If a health care provider, or a medical care facility agent or employee who is directly involved in the delivery of health care services, has knowledge that a health care provider has committed a reportable incident, such health care provider, agent or employee shall report such knowledge as follows:

(2) If the reportable incident occurred within a medical care facility, the report shall be made to the chief of the medical staff, chief administrative officer or risk manager of the facility. The chief of the medical staff, chief administrative officer or risk manager shall refer the report to the appropriate executive committee, which is duly constituted pursuant to the bylaws of the facility. The committee shall investigate all such reports and take appropriate action, including recommendation of a restriction of privileges at the appropriate medical care facility. In making its investigation, the committee may also consider treatment rendered by the health care provider outside the facility.

The committee shall have the duty to report to the appropriate state licensing agency any finding by the committee that a health care provider acted below the applicable probability of causing injury to a patient, or in a manner which may be grounds for disciplinary action by the appropriate licensing agency, so that the agency may take appropriate disciplinary measures.

R0820           **KSA 65-4923(a)(3)** If the health care provider involved in the reportable incident is a medical care facility, the report shall be made to the chief of the medical staff, chief administrative officer or risk manager of the facility. The chief of the medical staff, chief administrative officer or risk manager shall refer the report to the appropriate executive committee, which is duly constituted pursuant to the bylaws of the facility. The executive committee shall investigate all such reports and take appropriate action. The committee shall have the duty to report to the department of health and environment any finding that the facility acted in a manner, which is below the applicable standard of care and which has a reasonable probability of causing injury to a patient, so that appropriate disciplinary measures may be taken.

Each review and executive committee referred to in subsection (a) shall submit to the secretary of health and environment, on a form promulgated by such agency, at least once every three months, a report summarizing the reports received pursuant to subsections (a)(2) and (a)(3) of this section. The report shall include the number of reportable incidents reported, whether an investigation was conducted and any action taken.

R0826           **KAR 28-52-2(b)** (b) The risk manager, chief of staff, or administrator shall acknowledge the receipt of each incident report in writing. This acknowledgment may be made in the following manner:  
    (1) file stamping each report;  
    (2) maintaining a chronological risk management reporting log;  
    (3) signing or initialing each report in a consistent fashion; or  
    (4) entering pertinent information into a computer database.

R0828           **KAR 28-52-3(a)** Each medical care facility shall designate one or more executive committees responsible for making and documenting standard-of-care determinations with respect to each incident report, pursuant to K.A.R. 28-52-2. The jurisdiction of each risk management committee shall be clearly delineated in the facility's risk management plan, as approved by the facility's governing body.

R0829           **KAR 28-52-3(b)** The activities of each risk management committee shall be documented in its minutes at least quarterly, and this documentation shall demonstrate that the committee is exercising overall responsibility for standard-of-care determinations delegated by the committee to individual clinical reviewers and subordinate committees.

R0830           **KAR 28-52-4(a)** Each facility shall assure that analysis of patient care incidents complies with the definition of a "reportable incident" set forth at K.S.A. 65-4921.

R0831           **KAR 28-52-4(a)(1-4)** Each facility shall use categories to record its analysis of each incident, and those categories shall be in substantially the following form:  
    (1) Standards of care met;  
    (2) Standards of care not met, but with no reasonable probability of causing injury;  
    (3) Standards of care not met, with injury occurring or reasonably probable; or

(4) possible grounds for disciplinary action by the appropriate licensing agency.

R0832        **KAR 28-52-4(b)** Each reported incident shall be assigned an appropriate standard of care determination under the jurisdiction of a designated risk management committee. This regulation is cited when someone reports an incident to administration or risk management and that incident is not given a standard of care by the committee. It may, also, be cited when a facility gives a standard of care, which is obviously not appropriate for the incident.

R0833        **KAR 28-52-4(b)** Separate standard of care determinations shall be made for each provider and each clinical issue reasonably presented by the facts.

This deficient practice continues to be common. Each provider involved in an incident must receive a separate standard of care determination. Many times the facilities document a standard of care determination for the incident but do not look at each involved provider. The facility fails to evaluate the impact of the provider's involvement on the patient's outcome or potential outcome. Also this regulation is cited when the findings demonstrate more than one issue, but the facility makes only one standard of care determination.

R0835        **KAR 28-52-4(c)** Each standard-of-care determination shall be dated and signed by an appropriately credentialed clinician authorized to review patient care incidents on behalf of the designated committee.

R0836        **KAR 28-52-4(c)** Those cases in which documented primary review by individual clinicians or subordinate committees does not occur, standard-of-care determinations shall be documented in the minutes of the designated committee on a case-specific basis.